



Hepatitis C Drug Pricing – Request for Information

On August 7, 2018, the Louisiana Department of Health issued a Request For Information on the creation of a subscription-based payment model for Hepatitis C medication. Under this payment model, the state would pay a drug manufacturer or manufacturers for unlimited access to the treatment for the individuals in Louisiana who are enrolled in Medicaid or in Louisiana's correctional system. The payment to the manufacturer would be equal to or less than what the state is currently spending to provide the antiviral medication to these populations.

Hepatitis C is a lethal and contagious infection causing a public health crisis in Louisiana. About 30,000 people in Louisiana's Medicaid program and prison system are carrying Hepatitis C. The state cannot afford to treat large numbers of patients at current drug prices. Because of the high cost of the drug, less than 3% of this population was treated in Medicaid last year. Therefore, the Department is pursuing innovative payment models which will enable the state to dramatically expand access to the drug and eventually eliminate Hepatitis C as a public health problem.

[Click here](#) to review the complete Request for Information.

Overview of Request for Information Responses

In total, Louisiana received 13 responses to its Request for Information on Hepatitis C Drug Pricing, including two responses from providers, two from payers, and three from the pharmaceutical sector. The following is a brief overview; the full comments are also available for review.

Note: Not all respondents answered all of the questions listed within the Request for Information. Additionally, some respondents chose to redact information they deemed proprietary pursuant to 5 U.S.C. § 552(b)(4). The legal protection of such confidential commercial material is also claimed under the applicable provisions of 18 U.S.C. § 1905.

Summary of Responses

Providers

CrescentCare, a federally qualified health center in New Orleans, stated **“support [for] subscription as one option to treat the large number of Medicaid recipients currently unable to access a cure for hepatitis C.”** The health center would like to see all 70,000 Louisianans treated and proposed a 5 year time span, using strategies that include education campaigns, expanded screening, and rapid linkage to treatment. CrescentCare emphasized building upon existing HIV treatment infrastructure. They suggested that hepatitis C medication distribution should be run through “several well-vetted specialty pharmacies across the state” and cited a hub-and-spoke model. Additional services suggested for inclusion in an elimination campaign included syringe access, harm reduction training, and increased availability of co-located services, especially for opioid use disorder. CrescentCare asked the state to clarify how this model would interact with patient assistance programs.

Dr. Lauren Richey, an individual physician from Louisiana State University and co-director of an Infectious Disease clinic, responded with **“support [for] anything that expands access to treatment for people living with Hep C.”** Her response included support for opt-out screening in all health care

venues, expansion of prescription privileges to primary care providers. She noted that it would take time to build clinical capacity.

Payers

UnitedHealthcare stated that the company “**supports any and all efforts to increase curative treatments for hepatitis C**” while offering various issues for consideration. Healthy Blue, a subsidiary of Anthem, said, “We applaud the [Louisiana Department of Health] for exploring promotion, surveillance, and funding options as an initial step towards eliminating these barriers and helping all individuals with [hepatitis C] receive appropriate treatment.” Healthy Blue also stated that the model should include “sufficient flexibility and protections to avoid unexpected and undesired consequences”. Both respondents agreed that a hepatitis C elimination strategy should include the following elements:

1. An emphasis on coordination between the many treating entities, including federally qualified health centers, other health centers, and safety net hospitals. Healthy Blue notes that this coordination is especially important during the transition from incarceration to Medicaid, and asks the State to focus on transitions into managed care.
2. Easy access to screening and an expanded screening population. UnitedHealthcare suggested home testing.
3. Expansion of treatment to the majority of individuals with hepatitis C virus, which includes the removal of fibrosis requirements.
4. Expansion of prescribing privileges to non-specialists (e.g. primary care physicians) and other primary care providers (e.g. nurse practitioners). UnitedHealthcare suggested financial incentives for physicians to encourage testing and treating.
5. Access to case managers, ancillary services (e.g. transportation) to encourage patient compliance and reduce risky behaviors. Co-localization of services was encouraged.
6. A widespread education campaign for the public and a campaign for providers.

UnitedHealthcare presented data from their own members and expects to treat 350 unique members in 2018 out of a candidate population of 4400. Healthy Blue anticipated that in addition, 250 to 400 Louisianans will begin hepatitis C therapy within the next year under current policies.

With regard to carved-out pharmacy benefits, UnitedHealthcare supports a carve-out for hepatitis C medications, while Healthy Blue clearly states a preference for carved-in pharmacy benefits. UnitedHealthcare says that pharmacies should source directly from the manufacturer (two potential models are provided in the response), while Healthy Blue suggests that should hepatitis C medications be stocked in a virtual, distinct pharmacy. The companies noted several legal issues to be resolved. UnitedHealthcare asked the State to address treatment failure outside the subscription program, and to make financial plans for additional hepatitis C medications if necessary. Healthy Blue was concerned



that a contract might lock beneficiaries to one drug without accounting for new evidence, alternatives, or guidance.

Both respondents suggested that the Louisiana Department of Health utilize a broad-based steering committee which includes managed care organization representation. UnitedHealthcare offered to share the findings of their research on the viability of a subscription payment model in Louisiana.

Pharmaceutical Sector

Gilead Sciences, Inc. commented that “creative solutions are needed to reach the additional patients still living with HCV” and that **“Gilead is eager to consider a subscription payment model for curative HCV therapies.”** Such a model “could create predictable expenditures for the state while ensuring broad access as part of a [hepatitis C virus] elimination strategy.” Gilead pointed out the cost-effectiveness of this model to Medicaid, the potential for future savings to Medicare and other payors, and supported including people who are incarcerated. In terms of operationalizing the model, Gilead suggested that “the manufacturer... utilize the normal Medicaid drug rebate process to rebate the state the full amount paid for each bottle actually used. The rebate would be composed of the federal rebate required by section 1927 of the Social Security Act and a supplemental rebate that would rebate the remainder of the state’s purchase price for the drug.” Gilead further pointed out to opportunity presented by the subscription model to align incentives to “maximize patient access to curative therapy.”

The pharmaceutical manufacturers association PhRMA expressed support for **“state efforts to explore voluntary alternative financing arrangements, such as a subscription payment model”** and suggested it could be structured “as a CMS-approved supplemental rebate, with a state potentially paying a manufacturer an annual fixed fee for unlimited utilization of a manufacturer’s drug in the Medicaid program.” PhRMA urged the State to choose a model structure that would not to interrupt the care of existing patients and that would be administratively simple and affordable for community providers.

AbbVie commented that the company **“supports the national movement toward eliminating hepatitis C and shares the State’s goals for addressing the problem with Louisiana”** and encouraged the state to “consider establishing clearly defined and realistic goals, accompanied by defined milestones, to measures its progress towards eliminating hepatitis C.” AbbVie did not comment specifically on the subscription model, but stated the state should “explore the development of an internal task force and/or a joint task for or steering committee model...to provide insights and input on key decisions to help the State achieve goals.”

Others

The Boston Consulting Group expressed **“strong support [for] utilizing a subscription payment model to tackle the hepatitis C epidemic”** and provided additional information about the related concept of a “Payer Licensing Agreement.” They offered to help Louisiana compute an appropriate



subscription price. The Pew Charitable Trusts provided input on how to extend pricing to the correctional system through the 340B program. Brandi Bowen, a citizen from New Orleans, expressed support “if the model ensures patient choice, access, and a focus on the best possible treatment option” and called for “building capacity across systems” and “publicity/marketing campaigns.” The AIDS Institute supported “the state’s desire to increase [hepatitis C virus] treatment rates among the Medicaid, corrections and uninsured populations in order to cure people in the state of this potential deadly infectious disease” and urged Louisiana to expand access to hepatitis C treatment now through the Medicaid program.

Complete Responses



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1. Do you support a subscription payment model that tackles the public health crisis of Hepatitis C in Louisiana? Why or why not?

Answer 1:	<p>Healthy Blue is pleased to share our comments in response to the Louisiana Department of Health's Request for Information on Subscription Payment Models. We are pleased to suggest improvements and innovations for the Louisiana Department of Health (LDH) to consider regarding the upcoming Healthy Louisiana Request for Proposals (RFP) for Managed Care Organizations (MCOs). Healthy Blue proudly serves approximately 250,000 lives for Healthy Louisiana, and has been an incumbent since the Medicaid managed care program launched in 2012. Over 200 of our employees live throughout the state of Louisiana, providing a local commitment and understanding of the communities we serve. Healthy Blue also has the opportunity to pull from the national experience of our parent company, Anthem, Inc. Our family of affiliate health plans collectively serve more than 6.4 million people through state-sponsored programs in 21 markets. As an existing Healthy Louisiana MCO, we look forward to continuing our collaboration with LDH and Louisiana providers to improve the quality and value of care for Healthy Louisiana enrollees. We greatly appreciate the opportunity to participate in this information-gathering process and would be pleased to elaborate upon the following recommendations. We strongly support the goal of eliminating Hepatitis C virus (HCV) in Louisiana and applaud LDH for exploring innovative ways to expand therapy options to new populations. We believe that the prevalence of HCV infections in Louisiana will steadily decrease as more individuals become eligible for HPV therapy. Because most individuals that transition from incarceration are immediately eligible for Medicaid, LDH should initially focus on transitions into managed care where they can receive the most appropriate HCV therapy with appropriate care and linkages to community services. While we applaud LDH's desire to address this public health crisis, we encourage the state to construct the contract with sufficient flexibility and protections to avoid unexpected and undesired consequences associated with this model. While the current proposal could certainly improve the overall public health in Louisiana, there remains a debate regarding whether this approach is best adept at recognizing changes in clinical best practices, including advancements in modern medicine and new drug developments and approvals. The subscription payment model, as described in the RFI, emphasizes a particular brand, introducing clinical and cost of care concerns associated with programs that lock beneficiaries to a certain drug without accounting for emerging clinical evidence, cost-effective alternatives, and future FDA guidance. We believe the model should also address the critical need for additional wrap-around services for people who transmit disease via intravenous drug use or other value-added solutions that make pharmaceutical therapy management more</p>
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effective. MCOs are well-situated to address these additional needs. MCOs diligently monitor medical literature for guideline changes as well as Centers for Disease Control (CDC) and FDA updates. For example, Healthy Blue has adopted a number of best practices for the management of the prescription drug benefit, including establishing an independent Pharmacy and Therapeutics (P&T) Committee, which is comprised of two independent committees: □ A Clinical Review Committee (CRC) that is comprised of independent practicing physicians responsible for reviewing clinical trial data and literature of prescription drugs, focusing entirely on clinical efficacy, safety, and effectiveness. □ A Value Assessment Committee (VAC), which is responsible for making determinations with respect to the formulary and tiers in accordance with CRC decisions. The VAC considers financial factors in an effort to drive to a lowest net-cost coverage decision. These policy procedure committees are part of the rigorous decision-making processes that update our Prescription Drug List (PDL) and procedures quarterly to account for changes in clinical practice guidelines based on peer-reviewed literature and evidence-based medicine, safety recalls, an approved alternative competitor brand, new generic drugs, or emerging biosimilar drugs.

2. In addition to the Medicaid and corrections population, Louisiana is interested in exploring coverage for the uninsured as part of an elimination strategy. How could this strategy be expanded to cover some or all of the uninsured?

Answer 2: We applaud LDH for exploring promotion, surveillance, and funding options as an initial step toward eliminating these barriers and helping all individuals with HCV receive appropriate treatment. Despite the availability of highly effective therapy for HCV infection, barriers at multiple levels, from diagnosis to specialist referral, may impede the delivery of HCV care. At the patient level, lack of awareness, fear of side effects, poor adherence, and comorbid conditions may prevent treatment.[1] Providers must confront continuously changing medication options, navigate availability and authorization protocols, and communicate with hard to reach patients. To connect with uninsured individuals infected with HCV, we suggest that LDH collaborate with safety net providers such as Federally Qualified Health Centers (FQHCs), public health clinics, and local public health departments. FQHCs in partnership with community providers and the HRSA Health Center Program serve an essential role in helping to ensure that screenings are free and readily available in underserved areas. We also recommend emphasizing strong community partnerships to reach populations in housing units, schools, churches, and other community-based facilities. We suggest that LDH work closely with these providers regarding education, screening, and treatment. Additionally, managed care partners can develop high-touch programs to support state efforts. With experience in outreach strategies and integrated person-centered care, MCOs are uniquely situated to implement specialized disease management programs in support of state goals. MCOs develop partnerships to reach populations in housing units, schools, churches and other community-based facilities. Ensure Coordination between Corrections and MCOs We support the initiation of drug therapy for HCV in correctional settings and believe this is an important pillar to an elimination strategy. We suggest that, since most individuals that transition from incarceration are immediately eligible for Medicaid, close coordination with MCOs at the time of transition to the community is a vital component to ensuring continuity of care. MCOs assist with reentry and strive for continuing appropriate treatment, not just for HCV, but also for all medical and behavioral health conditions. Additionally, MCOs can arrange supports and referrals needed to address barriers to care, such as transportation, housing, and access to healthy food.

3. Under a subscription model, what strategies should the state use to identify people with Hepatitis C infection who are unaware of their infection? What should be done to increase awareness of Hep C and options for treatment?

Answer 3: To facilitate better identification of individuals with Hepatitis C infection and to help disseminate knowledge about treatment options, we strongly support the implementation of a widespread educational campaign consistent with the CDC Know More Hepatitis campaign, paired with easy access to screening. We encourage increased and easy access to screenings through FQHCs and community providers. For individuals enrolled in a managed care organization, we believe that advanced clinical analytics can be utilized to proactively identify infected individuals. The federal CDC and the U.S. Preventive Services Task Force (USPSTF) both recommend a one-time blood test for HCV for everyone born from 1945 to 1965. Healthy Blue supports this recommendation and would further advocate a single HCV test in each of the following cases: ☐ Current or former injection drug users, including those who injected only once many years ago ☐ Recipients of clotting factor concentrates made before 1987, when less advanced methods for manufacturing those products were used ☐ Recipients of blood transfusions or solid organ transplants prior to July 1992, before better testing of blood donations became available ☐ Chronic hemodialysis patients ☐ People with known exposures to HCV, such as health care workers after needle sticks involving HCV-positive blood recipients of blood or organs from a donor who tested HCV-positive ☐ People with HIV infection ☐ Children born to HCV-positive mothers We recommend using anti-HCV antibody testing to identify infected individuals based upon 2013 USPSTF recommendations. The USPSTF recommends HCV testing for: ☐ Incarcerated persons ☐ Persons who use intranasal drugs ☐ Persons who get an unregulated tattoo

4. How should Louisiana create the clinical capacity for distribution and treatment of DAAs for Hepatitis C?

Answer 4: We believe that the majority of individuals with HCV should be eligible for new combination therapies that are effective for all genotypes, and could be appropriately prescribed by non-specialists. We do not recommend implementing direct acting anti-viral drugs (DAAs) restrictions based on prescriber type. Medicaid MCOs already have established networks of primary care physicians and specialists in gastroenterology, hepatology, infectious diseases, and liver transplantation that create the clinical capacity for distribution and treatment of DAAs. DAAs promise shorter treatment times, much higher cure rates, and fewer side effects, but they cost much more than traditional medications, motivating many states to place restrictions on prescriber type to curb costs.

5. How should a subscription model account for the fact that a small percentage of patients may fail initial treatment or be reinfected?

Answer 5: We recommend the deployment of case managers and/or peer support specialists for the small percentage of patients that fail initial treatment or become reinfected, to help them restart a regimen. We also recommend focusing on transitions and other strategies for individuals who may return to corrections during a HCV treatment regimen. Additional lines of treatment and access to clinically equivalent competitor drugs enhance patient choice and allow members who fail a certain drug regimen additional options beyond what may be available under the well-intentioned subscription model. Healthy Blue is proud to have a robust formulary exception process for members who wish to pursue an array of pharmaceutical options.

6. How many patients do you anticipate being able to access curative treatment over this timeframe, categorized by population? Do you anticipate this to change by year, and if so, by how much?

Answer 6: Based upon our experience in Louisiana, we estimate that 250 to 400 individuals will begin HVC therapy within the next year. The range is driven by outreach efforts and eligibility standards.

7. For the managed Medicaid population, should this program be “carved out?”

Answer 7 We respect that in a time of uncontrollable list price increases perpetuated by pharmaceutical manufacturers, there is understandable frustration leveled at all players in the pharmaceutical supply chain. This includes MCOs and their contracted PBMs who work diligently to negotiate the best price on pharmacy benefits for their members. As a result, there is a growing desire among policymakers across states to “carve out” pharmacy benefits for the managed Medicaid population. While this provides the benefit of strict state pricing controls, and certainly, there is room for healthy debate, Healthy Blue believes our experience in managing our members’ care provides us a unique perspective on this matter. We believe maintaining a carved in pharmacy benefit within the Medicaid managed care benefit provides the ability and incentive for MCOs to coordinate care, integrate medical services and drug therapies, and improve quality of care and outcomes for beneficiaries. Our experience demonstrates that when services are carved out of the managed care benefit, MCOs lose the ability to fully manage these services as part of their overall care management approach. This leads to less effective overall care management and limits their impact on the total cost of care. Minimizing carve outs decreases fragmentation and reduces costs, while increasing beneficiary choice for HCV treatment coverage outside of a Fee-for-Service (FFS) agreement. Louisiana can benefit from the following advantages of having pharmacy benefits carved into Medicaid Managed Care: 1. Integrated quality care and improved care coordination 2. Increased beneficiary choice and consumer direction 3. Cost predictability and budget control 4. Improved member access to medications As Louisiana explores these arrangements, Healthy Blue recommends that certain guardrails be put in place around how these arrangements will impact MCO capitated payment rates. For example, for states with uniform PDLs, a consistent process should be established for how the value-based arrangement will be accounted for in PMPM rates for MCOs and how rebates will be collected by both MCOs and the state. This will help MCOs in constructing their rates. In addition, MCOs should be given the flexibility to adopt state value-based or outcomes-based arrangements. As previously stated, MCOs have significant experience with managing utilization and costs to deliver value and are best positioned to understand which strategies are most likely to be effective with their covered populations. To generate costs savings and most effectively steer patients toward cost-effective, high-value medications, MCOs should be provided the flexibility to either manage their own formularies or choose to adopt the state’s PDL and its negotiated discounts.

8. How should the DAAs be stocked, restocked and dispensed in a subscription model? What is the role of community pharmacies?

Answer 8: Healthy Blue believes participating community pharmacies would need to maintain a virtual, distinct inventory for dispensing HCV agents to qualified recipients. They would have to account for this virtual inventory separately from the standard inventory, in a manner similar to the 340b program manages their unique inventory. It would be the role of the community pharmacy to:

- ☐ Identify patients eligible for the program
- ☐ Assure appropriate drug utilization review (DUR) processes are in place
- ☐ Dispense the drug according to FDA labeling, ensuring appropriate (safe and efficacious) use
- ☐ Ensure no therapy duplication and not exceeding indicated dose or duration of therapy
- ☐ Adhere to the following process:
 - o Process the prescription to all insurance sources if the member has other health insurance: billing \$0 o

Maintain a de-identified invoicing process to get replacement supplies o The supplier would provide replacement inventory at no charge, and would pay the pharmacy dispensing fees. This should include any lost revenue that the pharmacy would have otherwise received o Report all dispenses to the state

9. What legal or regulatory issues does a subscription model raise and how can they be addressed through federal waivers (e.g., Medicaid Section 1115 waiver), pilot programs (e.g., those offered under the Center for Medicare and Medicaid Innovation), or regulatory guidance (e.g., from CMS or OIG)? Please be specific.

Answer 9: Healthy Blue supports moving the health care system towards paying for value instead of volume, and we have made great progress in moving hospital and physician payments to mechanisms where payments are tied to value. We support federal regulatory relief efforts to mitigate legal and regulatory barriers to value-based contracting for drugs, including creating safe harbors for "Medicaid Best Price" and anti-kickback statutes. In order to understand the impact that the Medicaid Drug Rebate Program and Best Price have on value-based arrangements, we recommend LDH focus first on developing and refining the goals and objectives for value-based arrangements through ongoing dialogue with stakeholders, including Medicaid MCOs. Current legal and regulatory barriers include: □ Section 1927 of the Social Security Act. This states that if a pharmaceutical manufacturer wishes to take advantage of guaranteed coverage of their products through Medicaid, the manufacturer simply needs to agree to provide a mandatory 23.1% rebate to the state, or the "best price" in the commercial market. This in means that for any drug that is FDA-approved for which the manufacturer has an active rebate agreement with the state Medicaid agency, the Medicaid agency must cover the drug on formulary and pay the cost of the drug set by the manufacturer, or assume liability. This current construct adds to the inflexible nature of the Medicaid Drug Rebate program, further hamstringing state budgets and diluting the ability of MCOs to effectively control drug spend. □ Anti-Kickback Statutes. Federal and state fraud and abuse laws are designed to protect patients, health plans, and the healthcare system overall from fraud, waste, and abuse. The Anti-Kickback Statute (AKS) prohibits offering or receiving remuneration (broadly defined) to induce or reward referrals for items or services paid for by federal healthcare programs. Statutory and regulatory safe harbors protect certain arrangements from AKS liability, but it is unclear how enforcement agencies would apply these safe harbors to value-based arrangements. AKS violations carry significant financial and other penalties. □ Best Price and Average Manufacturer Price. Implications for Best Price are the immediate, important factor to consider with respect to manufacturer incentives created by value-based contracting. Best Price is the pricing benchmark Medicaid uses to ensure state Medicaid programs never pay more than the lowest price offered for a particular therapy. Best Price is set based on the single "lowest price available from the manufacturer during the rebate period to any entity in the United States." Best Price is affected by manufacturer rebates, discounts, or other price concessions to commercial health plans, and setting a new Best Price can lead to significantly increased Medicaid rebate and 340B program liability for manufacturers. Under the current regulations, payments from manufacturers to health plans under a value-based contract would almost certainly need to be included in Best Price calculations. Concerning the Anti-Kickback Statute (AKS), there are regulatory and statutory safe harbors to protect some arrangements from liability, but it is not clear how enforcement agencies would apply these safe harbors. We recommend more discussions between state and federal partners to discuss the best way to create a regulatory and statutory environment that permits these arrangements.

10. What are key aspects of an elimination campaign that should complement a subscription model approach to antiviral medication?

Answer 10: We strongly support the implementation of a widespread educational campaign consistent with the CDC Know More Hepatitis campaign, paired with easy access to screening and treatment regardless of insurance. This campaign needs to include all payers as well as key community organizations. All payers should include information about HCV in their welcome materials, on their websites, and should send additional information to high-risk members. Inclusion of community leaders in screening campaigns can reduce the anxiety and stigma associated with screening. The Know More Hepatitis campaign is guided by behavioral science theories and extensive formative research. Healthy Blue recommends each of the following key strategies to supplement the elimination campaign that should complement a subscription model approach to antiviral medication: ☐ Television and radio public service announcements (PSAs) are aired on stations nationwide as donated placements and posted to CDC's website and a YouTube channel ☐ Print PSAs in the form of donated billboards, mall and transit ads, and airport dioramas are placed in major cities and local communities around the country ☐ Digital ads are purchased to drive consumers to view the PSAs or learn more about HCV on the campaign website ☐ Patient education materials including fact sheets, infographics, and posters are available for free in order to educate baby boomers about the importance of being tested for HCV ☐ Social media platforms such as Twitter, Facebook, and Vine disseminate campaign messages and materials ☐ Partner Tools like digital buttons and badges, videos, radio ads, and other materials help support the education and outreach efforts of state and local health departments

11. Is there anything else you would like to share with the Department related to our consideration of a subscription model?

Answer 11: We recommend that LDH convene a broad-based steering committee, including representation from the MCOs, to develop and implement a multi-pronged program to address HCV.

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1. Do you support a subscription payment model that tackles the public health crisis of Hepatitis C in Louisiana? Why or why not?

Answer 1:	<p>AbbVie supports the national movement toward eliminating hepatitis C and shares the State's goals for addressing this problem within Louisiana. AbbVie engages with civil society, government agencies, policy makers, and healthcare systems and professionals to support a wide range of efforts focused on making hepatitis C a public health priority and to explore approaches to eliminating the disease at both a local and a national level. AbbVie believes that an effective and efficient hepatitis C elimination approach must include the following foundational elements: – Build on current hepatitis C screening and diagnosis efforts. The State should be commended for its current screening and diagnosis initiatives. The State should look for opportunities to continue to improve the rate of diagnosis, including partnering with local stakeholders to identify the most effective approaches for locating undiagnosed hepatitis C patients. – Improving linkage to treatment. According to market data, an estimated 11% of diagnosed patients with hepatitis C in Louisiana were started on treatment between July 2017 and June 2018. This is an area of opportunity for the State, which should look to 1) align with institutions (as relevant to geographic area) to identify diagnosed patients in their system and link them to appropriate treatment, and 2) look to develop initiatives designed to motivate patients to seek treatment following their diagnosis. The State should consider removing non-clinically relevant treatment access restrictions (i.e. disease severity) so that the State can further its elimination objective by increasing the number of its residents that are eligible to access curative treatment. – Expanding the number of hepatitis C treaters. There are a limited number and type of prescribers (mainly specialists) who routinely treat hepatitis C in Louisiana. Expanding the number of treaters (beyond specialists) can be an important step in improving the State's ability to treat an increased number of patients seeking treatment. – Monitoring progress. AbbVie believes that data registries will be required to track progress, similar to the types of registries that have been implemented for other public health initiatives involving infectious diseases. In developing a broader strategy for addressing hepatitis C, the State should consider establishing clearly defined and realistic goals, accompanied by defined milestones, to measure its progress toward eliminating hepatitis C. In addition to the above, AbbVie encourages the State to focus on investing in initiatives that improve the "care cascade" — the journey experienced by hepatitis C patients from awareness to diagnosis to successful treatment. A phased approach to improving the care cascade may be the best option for identifying gaps in the current infrastructure. Several points for the State to consider are outlined below. Improving clinical capacity and treatment. Increasing the base</p>
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of health care professionals within Louisiana who regularly treat hepatitis C is an important component of any strategy for addressing the public health crisis. AbbVie is interested in understanding how it may be able to work with the State to support the education and training of healthcare professionals interested in treating hepatitis C. AbbVie is also interested in exploring additional opportunities with the State for building capabilities to improve clinical capacity and treatment, which may vary by geographic area within the State. As an important component of any hepatitis C elimination strategy, AbbVie recommends that the State consider interventions that target special populations that are disproportionately impacted by hepatitis C, including individuals who use drugs and the corrections population. AbbVie also recognizes that a small percentage of patients may fail initial treatment or be re-infected with the disease. In the market today, there are pangenotypic regimens with high efficacy and tolerable safety profiles with low discontinuation rates and many hepatitis C patients can be treated in as few as 8 weeks. A pangenotypic solution offers patients, providers, and policy makers the greatest opportunity for understanding and administering treatment to the entire population regardless of genotype, and in turn, helps the State see measurable results toward its objective of eliminating hepatitis C via a population-based approach in Louisiana. Improving patient education and awareness. The State has already taken an important step in laying the groundwork for addressing the hepatitis C epidemic through its screening and diagnosis efforts. Increasing patient education and awareness, particularly for those patients who are diagnosed but have not yet been linked to care, can be a critical component of any strategy to address the hepatitis C crisis. As part of any effective strategy, the State can consider implementing a comprehensive patient outreach campaign designed to identify, and motivate, new patients infected with hepatitis C to seek treatment. Such an approach may be best implemented through the collaboration of multiple stakeholders. Making use of AbbVie proprietary data. Improving treatment rates depends on several factors, including (1) the State's ability to continue improving screening and testing initiatives designed to diagnose new hepatitis C patients, (2) the State's ability to increase the base of hepatitis C treaters operating within the State, and (3) the State's ability to connect newly diagnosed patients to a hepatitis C treater. Depending on the State's timeframe for addressing these issues, AbbVie would be interested in exploring with the State how AbbVie's unique capabilities could be used to help develop an optimized clinical care model. AbbVie looks forward to the opportunity to meet with the State to share how our proprietary data capabilities could be helpful to Louisiana's efforts to improve treatment rates. Payment model considerations. As the State weighs the costs and benefits for various alternative payment models, we understand that further information and analysis may be needed to determine the budget impact of each approach. The State's desired duration and speed to reach its objectives may be most significant to consider. For example, the State could benefit from establishing its desired percentage of the Medicaid and corrections population to be treated over a 5-year horizon, with breakdowns by year. We welcome the opportunity to discuss with the State the data and analyses that we have undertaken to help the State determine its goals. Any state-wide initiative to address the hepatitis C crisis will be complex and certain considerations are likely to impact the State's total cost models. For example, small improvements — such as simpler care models, or treatment by generalists (primary care) — may yield larger potential cost savings. Similarly, the State may benefit from cost savings associated with reducing the rate of hepatitis C complications, such as liver transplants. The State may wish to consider beginning with a focused effort in a targeted geographic area or population to determine the most effective approaches for eliminating hepatitis C. Learnings from these initial efforts may help inform whether the models are scalable and what further infrastructure, stakeholders, and education may be needed. Distribution model considerations. Moreover, as part of its efforts to improve the care cascade, the State should take steps to ensure that the

	pharmacy distribution model is as simple and efficient as possible. The distribution model should consider the role of the designated wholesaler (as needed) and the pharmacies needed to support the State's initiatives. There also should be a person designated to handle the demand-planning aspects to ensure the timely delivery of drugs to patients with hepatitis C (both new starts and refills). The pharmacy plays a key role in navigating the prior authorization process to help patients gain access to treatment. The State should consider looking for ways to streamline the prior authorization process to enable a more efficient path for patients to have access to hepatitis C treatment.
2. In addition to the Medicaid and corrections population, Louisiana is interested in exploring coverage for the uninsured as part of an elimination strategy. How could this strategy be expanded to cover some or all of the uninsured?	
Answer 2:	Please see our response in question #1, which answers questions #1 through #11.
3. Under a subscription model, what strategies should the state use to identify people with Hepatitis C infection who are unaware of their infection? What should be done to increase awareness of Hep C and options for treatment?	
Answer 3:	Please see our response in question #1, which answers questions #1 through #11.
4. How should Louisiana create the clinical capacity for distribution and treatment of DAAs for Hepatitis C?	
Answer 4:	Please see our response in question #1, which answers questions #1 through #11.
5. How should a subscription model account for the fact that a small percentage of patients may fail initial treatment or be reinfected?	
Answer 5:	Please see our response in question #1, which answers questions #1 through #11.
6. How many patients do you anticipate being able to access curative treatment over this timeframe, categorized by population? Do you anticipate this to change by year, and if so, by how much?	
Answer 6:	Please see our response in question #1, which answers questions #1 through #11.
7. For the managed Medicaid population, should this program be "carved out?"	
Answer 7:	Please see our response in question #1, which answers questions #1 through #11.
8. How should the DAAs be stocked, restocked and dispensed in a subscription model? What is the role of community pharmacies?	
Answer 8:	Please see our response in question #1, which answers questions #1 through #11.
9. What legal or regulatory issues does a subscription model raise and how can they be addressed through federal waivers (e.g., Medicaid Section 1115 waiver), pilot programs (e.g., those offered under the Center for Medicare and Medicaid Innovation), or regulatory guidance (e.g., from CMS or OIG)? Please be specific.	
Answer 9:	Please see our response in question #1, which answers questions #1 through #11.

10. What are key aspects of an elimination campaign that should complement a subscription model approach to antiviral medication?

Answer 10: Please see our response in question #1, which answers questions #1 through #11.

11. Is there anything else you would like to share with the Department related to our consideration of a subscription model?

Answer 11: Please see our response in question #1, which answers questions #1 through #11.

If the commenter is a pharmaceutical company that manufactures a Hepatitis C treatment, we request attention to these questions in addition to the previous questions:

12. Is your company willing to consider a subscription model as outlined above?

Answer 12: Yes

13. Are there alternative cost-neutral or cost-saving models you propose to achieve Louisiana's goal?

Answer 13: Yes

14. What length of time would be appropriate for a subscription model contract for Hepatitis C treatment?

Answer 14: 5 years

15. What special payment considerations (e.g., use of the 340B program) should be considered to ensure access to curative treatment for each population?

Answer 15: Understanding what special payment considerations may be relevant to ensuring access to curative treatment for patient populations will depend on the overall strategy that the State of Louisiana decides to pursue for achieving its hepatitis C public health goals. While available funding is always an important consideration, it is also important for the State to ensure that a full complement of stakeholders are committed to implementing a comprehensive care model for treating hepatitis C.

16. In what ways would your company be able to support the public health and clinical infrastructure that will maximize access to curative treatment?

Answer 16: AbbVie has worked to identify barriers to treating patients with hepatitis C and is eager to explore how AbbVie may be able to be part of helping the Louisiana Department of Health build the capabilities required for eliminating hepatitis C.

17. Are there any other important considerations relevant to your potential participation in a subscription model?

Answer 17: As a potential starting point, we suggest that the State explore the development of an internal task force and/or a joint task force or steering committee model that could include representation from the private and public sectors, as well as academia (which the Department of Health has done in the recent past) in examining hepatitis C, to provide insights and input on key decisions to help the State achieve its goals. Regardless of model that the State ultimately pursues, AbbVie strongly encourages the State of Louisiana to consider removing all non-clinically relevant restrictions (i.e. disease severity) that limit patient access to medications, which is consistent with the AASLD clinical guidelines and guidance issued by the Centers for Medicare & Medicaid Services. Doing so offers the State the ability to ensure that clinically meaningful access exists for residents of the State who are living with

hepatitis C and who can benefit from today's curative treatments, while also positively impacting the overall public health of Louisiana and its elimination objective. In addition, AbbVie wishes to submit a few additional questions for the State to consider as it seeks to develop a strategy to address hepatitis C: – What are the State's plans to enroll uninsured patients in Medicaid? – How will the State ensure that uninsured patients seeking treatment are in-state residents? – How will the State manage patients who are under the care of the Department of Corrections? – How will the State address harm reduction of current injection drug users in order to prevent new Hepatitis C infections?

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1. Do you support a subscription payment model that tackles the public health crisis of Hepatitis C in Louisiana? Why or why not?

Answer 1: UnitedHealthcare Community & State (UnitedHealthcare) supports any and all efforts to increase access to curative therapies for hepatitis C. Although the subscription model has been feasible in other countries (namely Australia, Georgia, and some other markets), there are a number of financial, operational and regulatory barriers and considerations facing such a program in the United States. The most significant are: • Medicaid statutory rebate obligations for the pharmaceutical manufacturer • Medicaid Best Price requirements for the pharmaceutical manufacturer • Lack of federal matching funds for all but Medicaid beneficiaries • Actuarial considerations in Medicaid rate setting • The traditional distribution chain (manufacturer-wholesaler-pharmacy-patient) would have to be subverted to ensure that providers are not under-reimbursed by the subscription rates • Insufficient clinical infrastructure to treat and comprehensively care for those who are infected with HCV, especially among the incarcerated and uninsured populations • Unclear primary financial and clinical responsibility for those who are currently uninsured

2. In addition to the Medicaid and corrections population, Louisiana is interested in exploring coverage for the uninsured as part of an elimination strategy. How could this strategy be expanded to cover some or all of the uninsured?

Answer 2: The majority of the uninsured population has limited access to and utilization of both primary care and specialist services. As a result, HCV infection among the uninsured is almost certainly under-diagnosed, and those who have been diagnosed are less likely to have been treated. Additionally, those same issues of access to care create a barrier to diagnosing and treating uninsured Louisianans under the subscription model. To address these issues, LDH would likely need to partner with a number of entities, including local providers, the department of health, and jails/prisons. Federally Qualified Health Centers (FQHCs), Disproportionate Share Hospitals (DSHs), Community Health Centers (CHCs) are well suited for addressing the needs of the uninsured. These entities can provide free or discounted services to uninsured Louisianans, conducting HCV screenings and issuing prescriptions for those who are diagnosed. Public awareness and advertising campaigns may be needed to encourage the target population to pursue screening and treatment, and local providers may require additional resources (clinical and support staff, equipment, etc.) to handle the influx of new patients. Many among this population will be unable to pay for either the medical services or the prescriptions themselves, and may need to be subsidized by the State or other funding sources. Financial support for treatment of the uninsured presents another barrier, as federal matching funds are not available for non-Medicaid enrollees. Federal grants from philanthropic groups, additional state sources of funding, AHRQ, CMS, and CDC may be required to offset some of the additional costs incurred outside of Medicaid coverage, provided either to the State or directly to a facility partner. It is likely that a portion of the currently

uninsured population will qualify for Medicaid coverage, so outreach efforts within the subscription model could be reasonably expected to increase overall Medicaid enrollment.

3. Under a subscription model, what strategies should the state use to identify people with Hepatitis C infection who are unaware of their infection? What should be done to increase awareness of Hep C and options for treatment?

Answer 3: Other states have increased screening and awareness by providing incentives for primary care and specialist providers to conduct viral load tests. For example, state funds could be used to provide supplemental payments to providers who screen their patients. This is especially important for providers who treat baby boomers and those with a history of IV drug use, which are at disproportionately high risk of unknowingly contracting HCV. Other approaches could include publically subsidized kits that can facilitate home testing, use of broad-based community health worker campaigns to offer targeted or comprehensive testing in high risk populations or high risk geographies, new incentives to encourage point-of-care testing in primary care and other care settings. Additionally, convening expert groups with experience in broad based public health eradication efforts (e.g. World Health Organization and others) may uncover and inform novel strategies to ensure appropriate case identification. Traditional public education campaigns would likely also be beneficial for increasing awareness of treatment availability. The State could also work with local media outlets to promote advertising campaigns for whichever DAA manufacturer agrees to the subscription program.

4. How should Louisiana create the clinical capacity for distribution and treatment of DAAs for Hepatitis C?

Answer 4: Louisiana should leverage existing clinical infrastructure, particularly among Medicaid managed care plans to identify candidate patients and provide care services for their members (see response to question 7). For the uninsured, partnerships with FQHCs, DSHs, CHCs and other providers would be essential in ensuring that patients are identified and treated (see response to question (2)). Distribution of the DAA drugs themselves can follow a number of potential models, two of which are described in response to question (8). Critically, broad based treatment would require clinical training so non-specialists (such as primary care physicians and primary care nurse practitioners, for example, would be capable and able to successfully treat infected individuals. Additionally, as referenced in response to question (7), Medicaid Managed Care plans will likely be key in leveraging their existing provider networks to provide screening and care services to existing and newly enrolled Medicaid beneficiaries.

5. How should a subscription model account for the fact that a small percentage of patients may fail initial treatment or be reinfected?

Answer 5: It is likely that this number is likely to be very small (a few dozen individuals, based on epidemiological projections), assuming these individuals in fact complete their treatment courses. Those who fail their initial treatment with a DAA will need to be addressed outside of the subscription program, likely in a specialized setting. This will also require appropriate financial planning by the state. A patient who is unsuccessful with the DAA provided by the subscription model's pharmaceutical company will likely need a different drug, which would not be covered under the subscription agreement. For example, if Mavyret is the selected drug for the subscription program and a patient has adverse reaction or fails to reach sustained virologic response (SVR), the patient may need to be treated with Vosevi at full cost. Alternatively, the subscription model could be structured to allow only a single complete course per infected individual, and the state would accept that a small number of individuals would not be eligible for curative treatment.. Of note, most Medicaid programs currently limit the number of successful treatments to one per member over a lifetime. This policy could be changed to allow for those who are re-infected

after a successful cure to pursue a subsequent treatment under the subscription program. DAA products do not confer any resistance to re-infection, so it is possible that the same members would require treatment multiple times. This is especially likely among those who use illicit IV drugs. To limit the number of re-infections, ancillary support services for those engaging in high risk behaviors such as IV drug use may be warranted. Substance abuse treatment for this high risk population would likely incur additional costs outside of the subscription model, but would decrease the re-infection rate and improve both long-term costs and health outcomes.

6. How many patients do you anticipate being able to access curative treatment over this timeframe, categorized by population? Do you anticipate this to change by year, and if so, by how much?

Answer 6: As of late 2017, approximately 3,600 unique UHC members had a diagnosis of HCV on one or more claim in the prior two years. This represents approximately 0.84% of total membership at the time, which is slightly lower than the national prevalence of approximately 1.0% (2017 CDC estimates). As a result, UHC believes that HCV may be under-diagnosed among our membership, and that additional 700-800 cases may be undiagnosed at present, raising the total candidate population to approximately 4,400 unique individuals. UnitedHealthcare Community Plan of Louisiana treated 55 members for HCV in 2015, 82 in 2016 and 181 in 2017. At the current rate, UHC expects to treat approximately 350 unique members during 2018, bringing the total number treated with DAA products since 2015 to 669. These 669 treatments represent approximately 15% of the estimated HCV-infected population among UHC members, leaving more than 3,700 yet to be treated. At the current cost of Mavyret, which at \$26,000 before rebates is the cheapest available DAA, treating the remaining 3,700 members would cost yield a gross (pre-rebate) cost of approximately \$96,000,000. Assuming UHC's 15% treatment rate of diagnosed members is representative of the overall Louisiana population, nearly 62,000 of the 73,000 HCV-infected Louisianans still need to be cured. Using the same gross cost of Mavyret, these treatments would cost approximately \$1.6 Billion before applicable rebates. Revisions to the Medicaid coverage policies (removal of minimum fibrosis requirements) are expected to increase the treatment rate, independent of the subscription model. Based on our experience in other states, eliminating fibrosis requirements roughly doubles the number of expected treatments per year compared to policies with a minimum Metavir score of F3. This experience also suggests that even when fibrosis requirements are eliminated, patients with more advanced disease (F2+) pursue treatment at a far greater rate than those with less advanced fibrosis. This is likely a result of continuing stigma around hepatitis C treatments, which before the release of Sovaldi in late 2013, were marred by extreme side effects and low efficacy rates. This stigma and relatively low adoption highlights the need for a public awareness and education campaign as part of the subscription model in order to approach disease eradication in Louisiana.

7. For the managed Medicaid population, should this program be "carved out?"

Answer 7 Managed Care carve-out of the DAA drug products is likely the simplest option for all parties. This prevents any issues of adverse selection among managed care plans, and mitigates complexities related to MCO-PBM and PBM-Provider contracting issues. Carve-out allows LDH to directly control and simplify the distribution channels, and eliminates the need for complex actuarial adjustments in the existing rate setting process. However, managed care plans can and should play a significant role in development of the subscription model, to ensure proper incentives for broad based outreach and successful treatment of attributed patients. Managed Medicaid plans can leverage their provider networks to promote HCV screening, facilitate pre-and post-treatment viral load testing, and issue prescriptions for the selected DAA drugs.

8. How should the DAAs be stocked, restocked and dispensed in a subscription model? What is the role of community pharmacies?

Answer 8: In order to benefit from the cheaper subscription rate, pharmacies will have to source the drug product directly from the manufacturer, instead of through their typical wholesaler. It may be simplest to identify a preferred set of pharmacy providers who arrange to supply the drugs to eligible patients. The State would need to establish a payment mechanism for these pharmacies, likely following one of two models: Model (1) • Louisiana agrees to a subscription rate with manufacture, paid directly to the manufacturer o This could either be a decreased unit cost, or a single block payment • Drugs are sent to the selected pharmacy providers by the manufacturer (no wholesale charge) • Pharmacies submit claims with null ingredient costs to LDH, and are paid a dispensing or administration fee Model (2) • Louisiana agrees to a subscription rate with manufacture, paid directly to the manufacturer o This could either be a decreased unit cost, or a single block payment • Pharmacies purchase the drugs from their normal wholesalers and bill LDH for the prescription claims much like is done today, including drug rates and dispensing/administration fees • Manufacturer reimburses Louisiana for the incurred drug cost based on established terms • This model allows for a greater number of participating pharmacy providers, but exposes the manufacturer to markup charges by the wholesaler, pharmacy and PBM. o Although it is more scalable, this model likely entails a higher net cost per treatment.

9. What legal or regulatory issues does a subscription model raise and how can they be addressed through federal waivers (e.g., Medicaid Section 1115 waiver), pilot programs (e.g., those offered under the Center for Medicare and Medicaid Innovation), or regulatory guidance (e.g., from CMS or OIG)? Please be specific.

Answer 9: The most significant regulatory barriers presented by a subscription model are likely tied to Medicaid drug pricing rules, namely the obligation of drug manufacturers to pay statutory rebates for Medicaid utilization, and comply with Medicaid Best Price rules. Currently, manufacturers are required to pay rebates to Medicaid agencies (and CMS) for every unit (pill) of a covered drug that is dispensed to a Medicaid enrollee. This lowers the net cost of treatment in Medicaid, but if not subverted, creates a 'double-dipping' risk to drug manufacturers under a subscription model. Similarly, Medicaid Best Price rules stipulate that manufacturers must match the lowest net price offered to any private purchaser (excludes VA, DOD, Medicare Part D) for all Medicaid utilization by way of the statutory rebates. Hypothetically, if Louisiana were to reach a deal with a manufacturer for a deeper net discount on DAA drugs, the manufacturer would have to increase the rebates paid on that drug to all states for all Medicaid utilization from that point forward. Given these constraints, in order for drug manufacturers to be protected against large nation-wide profit loss, a subscription model for Louisiana would likely also have to include protections for the manufacturer. Such protection would likely entail an exemption for the drug manufacturer(s) from their obligation to pay statutory rebates on any utilization covered under the subscription model, and from the net price generated by the subscription model being included in subsequent Best Price calculations. Although there is no direct precedent for this kind of regulatory exemption in the United States, we believe that it may be achievable through a Medicaid Section 1115 waiver. In this scenario, CMS would allow claims for the DAA products from the selected manufacturers and dispensed in Louisiana to be excluded from statutory rebate invoicing and Medicaid best price calculations. An alternative waiver scenario entails Louisiana petitioning for the selected drug products to be removed from Medicaid Covered Drug status in the State, which would automatically negate both the rebates and the best price calculations. However, removing covered drug status may also exempt utilization for the selected products from qualifying for federal matching funds, furthering the overall funding gap for the program.

10. What are key aspects of an elimination campaign that should complement a subscription model approach to antiviral medication?

Answer 10: As referenced in response to prior questions, the most important compliments to a subscription model with the goal of eradication of HCV in Louisiana include bolstering the infrastructure of partnering clinical providers such as large provider systems, primary care centers, FQHCs, DSHs, CMCs and other local providers to support screening and treatment of the insured and uninsured. This infrastructure may also require innovative approaches to clinical care but also appropriate build outs of critical medical informatics programs to rack and facilitate treatment of patients seen in multiple settings, broad based clinical training and potentially distance-based support of non-urban providers, innovative use of community health workers, and other ingredients of successful eradication campaigns. Once these individuals are engaged for treatment of their HCV infection, they may also require treatment for other comorbidities, which represent a longer-term investment in their healthcare. In particular, adequate support for substance abuse treatment will be crucial, as the spread of HCV is likely to continue among this high risk population at an elevated rate. The ever-growing opioid crisis, and in fact, initial strategies to combat it, may lead to an increase in IV drug use, which leaves individuals at extremely high risk of contracting HCV and other infectious diseases. Any strategy aimed at eradicating HCV should also include consideration for substance abuse treatment services as a means of reducing the incidence of new infections and re-infections among those already cured.

11. Is there anything else you would like to share with the Department related to our consideration of a subscription model?

Answer 11: UHC and our sister company OptumLabs have been extensively researching the viability of a subscription model for treating HCV in Louisiana, and have established relationships with CMS and AbbVie pharmaceuticals, both of which have expressed interest in further exploring the pilot concept. We welcome the opportunity to share the detailed findings of our research and previous discussions with Louisiana, and would be excited to continue to serve as a collaborative partner in the pursuit of this initiative.

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1. Do you support a subscription payment model that tackles the public health crisis of Hepatitis C in Louisiana? Why or why not?

Answer 1: I may support it if the model ensures patient choice, access and a focus on the best possible treatment option.

2. In addition to the Medicaid and corrections population, Louisiana is interested in exploring coverage for the uninsured as part of an elimination strategy. How could this strategy be expanded to cover some or all of the uninsured?

Answer 2: Focus on building capacity across systems. To ensure the efficacy of this model, be aware of the time and resources necessary to ramp up HCV screening, public education, capacity for patient navigators/linkage coordinators, resources to assist with transportation to doctors appointments, case management support, etc. Working through existing safety net clinics (e.g. LPCA, 504HealthNet, Ryan White program, etc.) may be effective, but will take time and additional resources

3. Under a subscription model, what strategies should the state use to identify people with Hepatitis C infection who are unaware of their infection? What should be done to increase awareness of Hep C and options for treatment?

Answer 3: See answer #2 and be prepared to fully launch publicity/marketing campaigns. Institutional mindsets and community perception/comprehension of available care and treatment tends to take a long time to change (e.g. years). Be careful in the subscription contract... don't let the availability of medications run out at the same time everyone finally realizes there is help available. Maybe spend yr 1 building capacity/community awareness and then make the drugs available after yr 1, as an example of staggering how this is rolled out.

4. How should Louisiana create the clinical capacity for distribution and treatment of DAAs for Hepatitis C?

Answer 4: See answers 2 and 3

5. How should a subscription model account for the fact that a small percentage of patients may fail initial treatment or be reinfected?

Answer 5: I defer to clinical experts for this.

6. How many patients do you anticipate being able to access curative treatment over this timeframe, categorized by population? Do you anticipate this to change by year, and if so, by how much?

Answer 6: Experience has shown the time it takes to ramp up capacity for this kind of project should not be underestimated. I expect each year the program grows, word spreads, and patients share positive testimonials with peers the need will grow over time.

7. For the managed Medicaid population, should this program be “carved out?”

Answer 7 I defer to Medicaid experts for this question.

8. How should the DAAs be stocked, restocked and dispensed in a subscription model? What is the role of community pharmacies?

Answer 8: Not applicable to my expertise

9. What legal or regulatory issues does a subscription model raise and how can they be addressed through federal waivers (e.g., Medicaid Section 1115 waiver), pilot programs (e.g., those offered under the Center for Medicare and Medicaid Innovation), or regulatory guidance (e.g., from CMS or OIG)? Please be specific.

Answer 9:

10. What are key aspects of an elimination campaign that should complement a subscription model approach to antiviral medication?

Answer 10: Meet patients where they are. Provide patient educators/linkage coordinators/trained peers to help spread the word in the community and build community trust, i.e. community health workers.

11. Is there anything else you would like to share with the Department related to our consideration of a subscription model?

Answer 11: Keep it patient-centered. Do not assume the readiness of patients to be screened/ treated or their resources to make it work. Offer ancillary support when needed (e.g. peer educators, bus tokens). Similarly, some clinicians may need coaxing to adopt an HCV test and treat model. Thank you for considering this. Thank you for exploring innovative models to improve treatment access and for considering community input.

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1. Do you support a subscription payment model that tackles the public health crisis of Hepatitis C in Louisiana? Why or why not?

Answer 1: We strongly support utilizing a subscription payment model to tackle the Hepatitis C epidemic, in general, including for Louisiana! And we are elated that the State of Louisiana Office of Public Health is considering this option. We first introduced this pricing model, the Payer Licensing Agreement for Hepatitis C elimination, at the UCSF Global Health Economics Colloquium in February, 2018, in a talk titled "Learning from Netflix: a new drug licensing model to enable universal treatment access." We have spent the last year working on innovative pricing models and pricing model evolution across industries, particularly in healthcare, as part of our Fellowships in The Boston Consulting Group's think tank, The Henderson Institute. We have performed extensive academic research, in partnership with The Center for Disease Analysis, on the specific topic of pricing for Hepatitis C. We have a forthcoming paper under revision for publication in a peer-reviewed journal in which we lay out the economics and epidemiology that precisely make the case that the failure to eradicate Hepatitis C is largely a pricing model problem, and that a subscription payment model is the solution. We call such a subscription payment model a "Payer Licensing Agreement" (PLA). Our economic and epidemiological research shows that implementing a PLA for Hepatitis C could result in a "win-win-win" solution: universal patient access to treatment with disease eradication in ~5-7 years, far lower costs to payers, and with slightly greater pharmaceutical industry revenue. In our work to date, we have modeled the U.S. as a whole, as well as the U.K. and Italy, but the basic findings can be extrapolated to Louisiana specifically. We find that payer overall costs are reduced by more than 30% under a PLA versus status quo, mostly driven by significant cost-savings from reduced late-stage procedures. Treatment and cure volumes more than double in the first two years of program implementation. Liver-related deaths are reduced by ~60% versus status quo. Additionally, under a PLA, the state of Louisiana, as payer, has greater financial incentive to find, screen, treat, and cure its hepatitis C patients, in addition to its already great moral and social incentive to do so. This financial incentive comes from the zero incremental treatment cost necessary to cure additional patients (though finding and screening patients will still incur incremental cost). Given these many striking economic and epidemiological benefits we have modeled, we recommend the PLA model for Louisiana without hesitation. Further, we would welcome a conversation to discuss right-pricing, given the nature of the disease burden in Louisiana's prison and Medicaid populations. The first step is to model the broad costs Louisiana faces, as our colleague Homie Razavi and his team at CDA have done with your team earlier this year. However, negotiating an appropriate subscription price requires a nuanced look at the costs avoided by the system across patient cohorts, with a total that can be significantly lower than expected due to generalized cost assumptions. We are eager to help Louisiana in calculating an appropriate subscription price.

2. In addition to the Medicaid and corrections population, Louisiana is interested in exploring coverage for the uninsured as part of an elimination strategy. How could this strategy be expanded to cover some or all of the uninsured?

Answer 2: The premise of a PLA is that it is calculated based on the disease burden of a population, no matter how that population is defined. For example, according to the Drug Pricing Lab Louisiana Budget Allocator (cited in the RFI), there are 15,000 uninsured Louisianans with Hepatitis C. These 15,000 individuals could be added to the 30,000 individuals with hepatitis C who are on Medicaid or are incarcerated, as estimated by the Louisiana Department of Health. When setting the annual subscription price for the PLA, disease burden across the full eligible population will be necessary, along with assumptions around incidence rates for these patient segments. These data would be estimable through a combination of published work and, potentially, primary research.

3. Under a subscription model, what strategies should the state use to identify people with Hepatitis C infection who are unaware of their infection? What should be done to increase awareness of Hep C and options for treatment?

Answer 3: Hepatitis C screening and linkage to care is not our area of expertise, and we recommend the excellent work of FIND for ongoing research and informed perspective on this topic. However, two important considerations are below, which we have priced in to our models of PLA, and that we recommend Louisiana consider in its implementation. First, mandatory screening of prison populations is legal and straightforward, as are recommended screenings of individuals on Medicaid. Second, incentivizing individuals with Hepatitis C to take their own treatment is possible with a small cash inducement. New Zealand has implemented such a program to great effect. It is important in setting the "price" of this inducement that Louisiana not create perverse incentives in its lowest-income citizens; that is, the price cannot be so high that desperate individuals with low income would seek to contract the disease intentionally for the inducement.

4. How should Louisiana create the clinical capacity for distribution and treatment of DAAs for Hepatitis C?

Answer 4: We refrain from answering this question.

5. How should a subscription model account for the fact that a small percentage of patients may fail initial treatment or be reinfected?

Answer 5: There are at least two major questions within this question: one of logistics and leakage to care, one of pricing implications. We comment here only on pricing implications. A subscription model should by definition cover those who need treatment multiple times, and this situation should not lead to an increase in marginal costs to the state for treatment. Statistical probabilities of treatment failure and of reinfection can and should be modeled into the subscription price. If actual treatment failure and reinfection rates are significantly different from those estimated, one consideration as part of the PLA negotiation and contract is to cover marginal manufacturing costs of those drugs in excess. However, any contractual caveats to universal treatment access should be handled with extreme care.

6. How many patients do you anticipate being able to access curative treatment over this timeframe, categorized by population? Do you anticipate this to change by year, and if so, by how much?

Answer 6: We believe all individuals on Medicaid and in prison could access curative treatment over a 5 to 7 year timeframe. This will be heavily front-loaded in the first few years. The uninsured population is the most difficult to estimate, and will depend highly on the resources against effective screening and linkage to care programs.

7. For the managed Medicaid population, should this program be "carved out?"

Answer 7: We refrain from answering this question.

8. How should the DAAs be stocked, restocked and dispensed in a subscription model? What is the role of community pharmacies?

Answer 8: We refrain from answering this question.

9. What legal or regulatory issues does a subscription model raise and how can they be addressed through federal waivers (e.g., Medicaid Section 1115 waiver), pilot programs (e.g., those offered under the Center for Medicare and Medicaid Innovation), or regulatory guidance (e.g., from CMS or OIG)? Please be specific.

Answer 9: We refrain from answering this question.

10. What are key aspects of an elimination campaign that should complement a subscription model approach to antiviral medication?

Answer 10: As mentioned in a previous answer, Louisiana should consider incentivizing individuals with Hepatitis C to take their own DAA treatment by providing a small cash inducement. New Zealand has implemented such a program to great effect. In setting the "price" of this inducement, Louisiana must take care to not create perverse incentives in its lowest-income citizens; that is, the price cannot be so high that desperate individuals with low income would seek to contract the disease intentionally for a cash inducement. We have priced this consideration into our economic modeling efforts.

11. Is there anything else you would like to share with the Department related to our consideration of a subscription model?

Answer 11: We would welcome a conversation to explore the possibility of collaborating on this topic, which we have studied in detail after devising the Payer Licensing Agreement for hepatitis C. Further, we invite a conversation to discuss right-pricing, given the nature of the disease burden in Louisiana's prison and Medicaid populations. We are eager to help Louisiana in computing an appropriate subscription price, which is a fraught and nuanced calculation. Finally we think one of issue that needs to be thought through and manage is the eventuality that people would move from other States to Louisiana in order to get access to the treatment. Biopharma companies would see this as a potential cannibalization risk that they will want to manage. We think there are ways to manage this but it the issue will need to be addressed.

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1. Do you support a subscription payment model that tackles the public health crisis of Hepatitis C in Louisiana? Why or why not?

Answer 1: Since Gilead launched Sovaldi in 2013, nearly 1 million patients have been treated with hepatitis C (HCV) direct-acting antivirals (DAAs) in the United States. However, creative solutions are needed to reach the additional patients still living with HCV, and we are supportive of a subscription payment model for curative HCV therapies as one of these solutions. The launch of HCV cures led to widespread recognition that curative therapies are often in high demand and may have a significant initial budget impact. Structural solutions are required, especially in public programs, that help to close the gap between the initial cost of a cure and the savings that accrue over time. This has led to a short-term affordability and predictability challenge for many payors. In an effort to mitigate these challenges, we have carefully considered long-term financing options that could be appropriate for curative therapies such as HCV. Therefore, Gilead is eager to consider a subscription payment model for curative HCV therapies. A Medicaid subscription model for cures could create predictable expenditures for the state while ensuring broad access as part of an HCV elimination campaign. This model could enhance and accelerate HCV elimination efforts such as screening and linkage to care and building treatment capacity. In addition to being cost-effective for Medicaid (Chou et al.), a subscription approach has spill-over benefits to other payors, including Medicare. Many of the Medicaid patients eventually age into Medicare, and curing patients of HCV early in the stage of their disease has been shown to be cost-effective and cost-saving by eliminating the need for chronic treatment costs. As described in the responses to the following questions, we define a subscription model as a fixed fee that the State would pay a manufacturer each year for HCV treatment over a set number of years, such as five years. The manufacturer would then utilize the normal Medicaid drug rebate process to rebate the state the full amount paid for each bottle actually used. The rebate would be composed of the federal rebate required by section 1927 of the Social Security Act and a supplemental rebate that would rebate the remainder of the state's purchase price for the drug. The state would be able to treat as many patients as possible, while enabling predictability to its drug spending. As a result, this model would align the system incentives to maximize patient access to curative therapy. There are variations on this model, such as inclusion of correctional populations in a Medicaid subscription payment, that are described in more detail below. While a subscription payment model may help address the short-term affordability challenge of curative therapies, this model would not be appropriate for chronic therapies given the longer-term nature of the treatment period. 1. Chou JW, Silverstein AR, Goldman DP. Impact of Medicaid Treatment Access Policies on the Hepatitis C Epidemic. Presented at the ISPOR 23rd Annual International Meeting - May 19-23, 2018, Baltimore, MD, USA.

2. In addition to the Medicaid and corrections population, Louisiana is interested in exploring coverage for the uninsured as part of an elimination strategy. How could this strategy be expanded to cover some or all of the uninsured?

Answer 2: [redacted]

3. Under a subscription model, what strategies should the state use to identify people with Hepatitis C infection who are unaware of their infection? What should be done to increase awareness of Hep C and options for treatment?

Answer 3: [redacted]

4. How should Louisiana create the clinical capacity for distribution and treatment of DAAs for Hepatitis C?

Answer 4: [redacted]

5. How should a subscription model account for the fact that a small percentage of patients may fail initial treatment or be reinfect?

Answer 5: [redacted]

6. How many patients do you anticipate being able to access curative treatment over this timeframe, categorized by population? Do you anticipate this to change by year, and if so, by how much?

Answer 6: [redacted]

7. For the managed Medicaid population, should this program be “carved out?”

Answer 7 [redacted]

8. How should the DAAs be stocked, restocked and dispensed in a subscription model? What is the role of community pharmacies?

Answer 8: [redacted]

9. What legal or regulatory issues does a subscription model raise and how can they be addressed through federal waivers (e.g., Medicaid Section 1115 waiver), pilot programs (e.g., those offered under the Center for Medicare and Medicaid Innovation), or regulatory guidance (e.g., from CMS or OIG)? Please be specific.

Answer 9: [redacted]

10. What are key aspects of an elimination campaign that should complement a subscription model approach to antiviral medication?

Answer 10: [redacted]

11. Is there anything else you would like to share with the Department related to our consideration of a subscription model?

Answer 11:

If the commenter is a pharmaceutical company that manufactures a Hepatitis C treatment, we request attention to these questions in addition to the previous questions:

12. Is your company willing to consider a subscription model as outlined above?

Answer 12: [redacted]

13. Are there alternative cost-neutral or cost-saving models you propose to achieve Louisiana’s goal?

Answer 13: [redacted]

14. What length of time would be appropriate for a subscription model contract for Hepatitis C treatment?

Answer 14 [redacted]

15. What special payment considerations (e.g., use of the 340B program) should be considered to ensure access to curative treatment for each population?

Answer 15: [redacted]

16. In what ways would your company be able to support the public health and clinical infrastructure that will maximize access to curative treatment?

Answer 16: [redacted]

17. Are there any other important considerations relevant to your potential participation in a subscription model?

Answer 17: [redacted]



Re: Request for Information on Subscription Payment Models (HCV RFI)

Dear Secretary Gee,

AbbVie appreciates this opportunity to comment on the Louisiana Department of Health's request for information related to hepatitis C. AbbVie acknowledges the commitment by the State in pursuing potential ways to eliminate hepatitis C, and looks forward to the opportunity to further explore how we could work with the State to help it achieve its objectives.

AbbVie has a long history in the field of infectious diseases, including HIV and hepatitis C, and believes that our extensive clinical, epidemiologic, research, and market expertise, along with our proprietary data capabilities, could help the State optimize its approach to eliminating hepatitis C across the state.

GENERAL COMMENTS

AbbVie supports the national movement toward eliminating hepatitis C and shares the State's goals for addressing this problem within Louisiana. AbbVie engages with civil society, government agencies, policy makers, and healthcare systems and professionals to support a wide range of efforts focused on making hepatitis C a public health priority and to explore approaches to eliminating the disease at both a local and a national level.

AbbVie believes that an effective and efficient hepatitis C elimination approach must include the following foundational elements:

- Build on current hepatitis C screening and diagnosis efforts. The State should be commended for its current screening and diagnosis initiatives. The State should look for opportunities to continue to improve the rate of diagnosis, including partnering with local stakeholders to identify the most effective approaches for locating undiagnosed hepatitis C patients.
- Improving linkage to treatment. According to market data, an estimated 11% of diagnosed patients with hepatitis C in Louisiana were started on treatment between July 2017 and June 2018. This is an area of opportunity for the State, which should look to 1) align with institutions (as relevant to geographic area) to identify diagnosed patients in their system and link them to appropriate treatment, and 2) look to develop initiatives designed to motivate patients to seek treatment following their diagnosis. The State should consider removing non-clinically relevant treatment access restrictions (i.e. disease severity) so that the State can further its elimination objective by increasing the number of its residents that are eligible to access curative treatment.
- Expanding the number of hepatitis C treaters. There are a limited number and type of prescribers (mainly specialists) who routinely treat hepatitis C in

Louisiana. Expanding the number of treaters (beyond specialists) can be an important step in improving the State's ability to treat an increased number of patients seeking treatment.

- **Monitoring progress.** AbbVie believes that data registries will be required to track progress, similar to the types of registries that have been implemented for other public health initiatives involving infectious diseases. In developing a broader strategy for addressing hepatitis C, the State should consider establishing clearly defined and realistic goals, accompanied by defined milestones, to measure its progress toward eliminating hepatitis C.

In addition to the above, AbbVie encourages the State to focus on investing in initiatives that improve the “care cascade” — the journey experienced by hepatitis C patients from awareness to diagnosis to successful treatment. A phased approach to improving the care cascade may be the best option for identifying gaps in the current infrastructure. Several points for the State to consider are outlined below.

Improving clinical capacity and treatment. Increasing the base of health care professionals within Louisiana who regularly treat hepatitis C is an important component of any strategy for addressing the public health crisis. AbbVie is interested in understanding how it may be able to work with the State to support the education and training of healthcare professionals interested in treating hepatitis C. AbbVie is also interested in exploring additional opportunities with the State for building capabilities to improve clinical capacity and treatment, which may vary by geographic area within the State.

As an important component of any hepatitis C elimination strategy, AbbVie recommends that the State consider interventions that target special populations that are disproportionately impacted by hepatitis C, including individuals who use drugs and the corrections population. AbbVie also recognizes that a small percentage of patients may fail initial treatment or be reinfected with the disease. In the market today, there are pangenotypic regimens with high efficacy and tolerable safety profiles with low discontinuation rates and many hepatitis C patients can be treated in as few as 8 weeks. A pangenotypic solution offers patients, providers, and policy makers the greatest opportunity for understanding and administering treatment to the entire population regardless of genotype, and in turn, helps the State see measurable results toward its objective of eliminating hepatitis C via a population-based approach in Louisiana.

Improving patient education and awareness. The State has already taken an important step in laying the groundwork for addressing the hepatitis C epidemic through its screening and diagnosis efforts. Increasing patient education and awareness, particularly for those patients who are diagnosed but have not yet been linked to care, can be a critical component of any strategy to address the hepatitis C crisis. As part of any effective strategy, the State can consider implementing a comprehensive patient outreach campaign designed to identify, and motivate, new patients infected with

hepatitis C to seek treatment. Such an approach may be best implemented through the collaboration of multiple stakeholders.

Making use of AbbVie proprietary data. Improving treatment rates depends on several factors, including (1) the State's ability to continue improving screening and testing initiatives designed to diagnose new hepatitis C patients, (2) the State's ability to increase the base of hepatitis C treaters operating within the State, and (3) the State's ability to connect newly diagnosed patients to a hepatitis C treater. Depending on the State's timeframe for addressing these issues, AbbVie would be interested in exploring with the State how AbbVie's unique capabilities could be used to help develop an optimized clinical care model. AbbVie looks forward to the opportunity to meet with the State to share how our proprietary data capabilities could be helpful to Louisiana's efforts to improve treatment rates.

Payment model considerations. As the State weighs the costs and benefits for various alternative payment models, we understand that further information and analysis may be needed to determine the budget impact of each approach. The State's desired duration and speed to reach its objectives may be most significant to consider. For example, the State could benefit from establishing its desired percentage of the Medicaid and corrections population to be treated over a 5-year horizon, with breakdowns by year. We welcome the opportunity to discuss with the State the data and analyses that we have undertaken to help the State determine its goals.

Any state-wide initiative to address the hepatitis C crisis will be complex and certain considerations are likely to impact the State's total cost models. For example, small improvements — such as simpler care models, or treatment by generalists (primary care) — may yield larger potential cost savings. Similarly, the State may benefit from cost savings associated with reducing the rate of hepatitis C complications, such as liver transplants. The State may wish to consider beginning with a focused effort in a targeted geographic area or population to determine the most effective approaches for eliminating hepatitis C. Learnings from these initial efforts may help inform whether the models are scalable and what further infrastructure, stakeholders, and education may be needed.

Distribution model considerations. Moreover, as part of its efforts to improve the care cascade, the State should take steps to ensure that the pharmacy distribution model is as simple and efficient as possible. The distribution model should consider the role of the designated wholesaler (as needed) and the pharmacies needed to support the State's initiatives. There also should be a person designated to handle the demand-planning aspects to ensure the timely delivery of drugs to patients with hepatitis C (both new starts and refills). The pharmacy plays a key role in navigating the prior authorization process to help patients gain access to treatment. The State should consider looking for ways to streamline the prior authorization process to enable a more efficient path for patients to have access to hepatitis C treatment.

RESPONSE TO SPECIFIC QUESTIONS



In addition to the general comments set forth above, AbbVie is also pleased to respond to the specific questions that the Louisiana Department of Health has asked pharmaceutical companies to address.

12. Is your company willing to consider a subscription model as outlined above?

AbbVie looks forward to meeting with the State of Louisiana to discuss alternative payment models, as well as solutions to address the gaps in the care cascade in an effort to help the State achieve its goal of eliminating hepatitis C.

13. Are there alternative cost-neutral or cost-savings models you propose to achieve Louisiana's goals?

AbbVie looks forward to meeting with the State of Louisiana to discuss the range of alternative payment models and understand which approach could work best in helping the State achieve its goals. Because any state-wide initiative to address hepatitis C would be a complex undertaking, identifying an appropriate model depends on the overall strategy that Louisiana decides to pursue. AbbVie strongly believes that a comprehensive, multi-stakeholder strategy is needed if the State is going to be successful in achieving its goals. AbbVie looks forward to contributing its knowledge as the State develops an effective strategy and to identify appropriate models to implement that strategy.

14. What length of time would be appropriate for a subscription model contract for Hepatitis C treatment?

The appropriate length of time to apply any alternative payment model will be determined based on the nature of State's comprehensive strategy for eliminating hepatitis C as a public health problem, as well as the expected duration and speed that the State has determined is appropriate to achieve its specific goals. We look forward to learning more about this from our discussions with the State and through any future potential request for proposal that the State may choose to issue.

In setting its own benchmarks, the Louisiana Department of Health may wish to refer to the goals set by the World Health Organization to track progress towards eliminating viral hepatitis. The World Health Organization's Global Health Sector Strategy on Viral Hepatitis¹

¹ WHO, Global Health Sector Strategy on Viral Hepatitis, 2016-2021, <http://www.who.int/hepatitis/strategy2016-2021/ghss-hep/en/>; WHO Advocacy Brief, Combating Hepatitis B & C to Reach Elimination by 2030, <http://www.who.int/hepatitis/publications/hep-elimination-by-2030-brief/en/>



seeks to achieve a 65 percent reduction in mortality from hepatitis C, and includes the following milestones:

2020 Milestones:

- Diagnose 30 percent of patients with hepatitis C
- Ensure 95 percent safe blood screening practices
- Provide 200 syringe/needle sets to each injecting drug user each year

2030 Milestones:

- Diagnose 90 percent of patients with hepatitis C
- Treat 80 percent of all patients with hepatitis C
- Ensure 100 percent safe blood screening practices
- Provide 300 syringe/needle sets to each injecting drug user each year

15. What special payment considerations (e.g., use of the 340B program) should be considered to ensure access to curative treatment for each population?

Understanding what special payment considerations may be relevant to ensuring access to curative treatment for patient populations will depend on the overall strategy that the State of Louisiana decides to pursue for achieving its hepatitis C public health goals. While available funding is always an important consideration, it is also important for the State to ensure that a full complement of stakeholders are committed to implementing a comprehensive care model for treating hepatitis C.

16. In what ways would your company be able to support the public health and clinical infrastructure that will maximize access to curative treatment?

AbbVie has worked to identify barriers to treating patients with hepatitis C and is eager to explore how AbbVie may be able to be part of helping the Louisiana Department of Health build the capabilities required for eliminating hepatitis C.

17. Are there any other important considerations relevant to your potential participation in a subscription model?

As a potential starting point, we suggest that the State explore the development of an internal task force and/or a joint task force or steering committee model that could include representation from the private and public sectors, as well as academia (which the Department of Health has done in the recent past) in examining hepatitis C, to provide insights and input on key decisions to help the State achieve its goals.

Regardless of model that the State ultimately pursues, AbbVie strongly encourages the State of Louisiana to consider removing all non-clinically relevant restrictions (i.e. disease severity) that limit patient access to medications, which is consistent with the



AASLD clinical guidelines² and guidance issued by the Centers for Medicare & Medicaid Services³. Doing so offers the State the ability to ensure that clinically meaningful access exists for residents of the State who are living with hepatitis C and who can benefit from today's curative treatments, while also positively impacting the overall public health of Louisiana and its elimination objective.

In addition, AbbVie wishes to submit a few additional questions for the State to consider as it seeks to develop a strategy to address hepatitis C:

- What are the State's plans to enroll uninsured patients in Medicaid?
- How will the State ensure that uninsured patients seeking treatment are in-state residents?
- How will the State manage patients who are under the care of the Department of Corrections?
- How will the State address harm reduction of current injection drug users in order to prevent new Hepatitis C infections?

Thank you again for the opportunity to comment on this RFI, and we look forward to continuing our discussions with the Department of Health on how we may work together to meaningfully address hepatitis C in Louisiana.

Sincerely,
Annika Lane
General Manager
U.S. Hepatology and Virology
AbbVie

² HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C." *HCVguidelines.org*, American Association for the Study of Liver Diseases (AASLD), <https://www.hcvguidelines.org/>

³ Assuring Medicaid Beneficiaries have Access to Hepatitis C (HCV) Drugs." *Medicaid.gov*, The Centers for Medicare & Medicaid Services (CMS), 5 Oct. 2015, <https://www.medicaid.gov/medicaid-chip-programinformation/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf>



RE: RFI regarding Subscription Payment Models for Hepatitis C Drugs

Dear Dr. Gee:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Louisiana Department of Health's Request for Information (RFI) on subscription payment models for Hepatitis C drugs. BIO is committed to working in partnership with states, the Centers for Medicare and Medicaid Services (CMS), and other stakeholders to develop innovative payment models to ensure patient access to novel therapies.

BIO is the largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than thirty other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In these ways, our members' novel therapeutics, vaccines, and diagnostics yield not only improved health outcomes, but also reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

There is perhaps no better example of how innovations in biopharmaceutical research can impact disease treatment and reduce costs than by looking at the recent history of Hepatitis C. Because of advances in biotechnology, a once chronic and potentially fatal disease affecting millions of Americans, is now curable in over 90% of patients. These cures bring significant value to payers, providers, and our entire healthcare system by reducing the long-term costs associated with managing Hepatitis C. As more patients gain access to these new treatments, we can expect to see a significant decline in the staggering costs of treating this disease.

Despite these advancements, and increased competition in the market, patient access remains a concern. As you know, the significant size of the Hepatitis C patient population that is yet to be treated puts significant short-term financial pressures on payers, particularly state Medicaid programs. In such a situation, innovative strategies are necessary to ensure patients have access to treatments that will cure this devastating disease. To that end, BIO strongly supports the development of innovative payment and reimbursement models aimed at increasing patient access. Innovative payment strategies may include a range of approaches, including value-based payment, risk pools, reinsurance, or paying for therapies over time through annuity models, such as the subscription-based model proposed by Louisiana.

We believe that innovative payment strategies, such as the subscription payment model proposed by Louisiana, could provide an avenue for ensuring access to curative therapies such as those for Hepatitis C. Such novel payment and financing models have the potential to better align costs with the time-period over which benefits are delivered to the patient and overall healthcare system. As currently envisioned, we believe that a subscription model works best in the context of curative therapies such as the Hepatitis C drugs, in which the course of therapy is completed with immediate value to the health system. The patient is cured and there are no additional costs beyond the contract period for the drug.

Key Issues

Despite the promise of innovative payment approaches to ensure patient access, significant issues and impediments remain. BIO believes that patient access should remain a top area of concern for the state when structuring such a payment model. If this payment model is indeed implemented, there should be consideration given to patients that are already undergoing a therapy that is different than a drug newly covered under the subscription model, or new patients for whom their physician has determined will respond better to a different Hepatitis C medication. Patients respond to Hepatitis C medications differently depending upon the HCV genotype they have. There should be exceptions and appeals processes to ensure patients have access to the drugs their doctor believes will work best for them.

Another area of concern is that the state would likely need to request and receive approval from CMS in the form of a waiver before embarking on such a program, since it diverges from current statute. Moreover, innovative payment models, including a subscription payment model, raise concerns under Medicaid's best price reporting requirements. Clear exceptions to the Medicaid best price reporting requirements would be needed to ensure that innovative payment models, such as a subscription-based model, can succeed.

In addition to government price reporting considerations, the Medicare and Medicaid programs are subject to the Anti-Kickback Statute (AKS), which raises significant concerns and uncertainties for manufacturers interested in exploring innovative payment strategies. "The Anti-Kickback Statute makes it a criminal offense to knowingly and willfully provide something of value with the intent to induce the purchase of items or services payable by a federal health care program."¹ The Department of Health and Human Services Office of Inspector General (OIG) must modernize its safe harbor provisions under the AKS. The OIG should develop new safe harbors specific to certain services often incorporated into innovative payment strategies (e.g., data analytics, adherence support). Modernizing the AKS safe harbors will help promote the adoption of innovative payment approaches, including those envisioned under a subscription payment model, that could improve health outcomes and reduce costs to Federal and state healthcare programs – both criteria for modifying and establishing safe harbor provisions.²

Moreover, we believe the state would need to examine issues regarding contract and price reporting under Medicaid. While developing novel payment models, it is important to examine any contractual obligations of being in the Medicaid state purchasing pool (TOP\$). The state would need to assess whether anything offered to Louisiana by a biopharmaceutical manufacturer would need to be made available to all TOP\$ members. This could impact negotiations significantly. Also, we believe the state should consider how its potential model will comply with the need for the manufacturer to manage product pricing, which needs to be allocated on a per unit basis for the purposes of complying with price reporting regulations that require reporting on a per unit versus per patient basis.

1 AMCP Partnership Forum: Advancing Value-Based Contracting, White Paper, JMCP, November 2017.

2 80 Fed. Reg. at 79,805.



Thank you for the opportunity to comment on the RFI regarding a subscription payment model for Hepatitis C direct-acting antivirals. We look forward to working with the State of Louisiana to develop effective alternative payment models for curative and transformative therapies. Should you have any questions regarding our comments, please do not hesitate to contact me at 202-962-9200.

Sincerely,

/s/

Jack Geisser

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1. Do you support a subscription payment model that tackles the public health crisis of Hepatitis C in Louisiana? Why or why not?	
Answer 1:	As a physician who specializes in infectious diseases and treats Hep C, I support anything that expands access to treatment for people living with Hep C.
2. In addition to the Medicaid and corrections population, Louisiana is interested in exploring coverage for the uninsured as part of an elimination strategy. How could this strategy be expanded to cover some or all of the uninsured?	
Answer 2:	I am not sure. There are required labs and imaging that are needed to make clinical decisions about therapy. Free drugs are only helpful if the other services are available. I work at UMC and have access to free care so I can treat and get meds through patient assistance for uninsured patients but I am not sure if that would work in non-public hospitals.
3. Under a subscription model, what strategies should the state use to identify people with Hepatitis C infection who are unaware of their infection? What should be done to increase awareness of Hep C and options for treatment?	
Answer 3:	The only way to truly identify everyone with Hep C would be to do opt out testing in all healthcare venues. It would work. Also offering free testing at needle exchanges, rehabs and primary care clinics.
4. How should Louisiana create the clinical capacity for distribution and treatment of DAAs for Hepatitis C?	
Answer 4:	Clinical capacity would take years to build. Even the hiring, credentialing and training of appropriately qualified providers would still take a lot of time. Given how disheartening the current treatment landscape is for Hep C not many providers have been interested in it. Telling people that curative therapy exists but isn't available to them has not made many people want to have extra clinics or go into the field, especially among students, residents and fellows. This could take years to change. I am not sure primary care would be willing to treat Hep C. They refer even the simplest infections currently (+PPD, cellulitis etc). The clinic I co-direct at the ID Center at UMC has a booming Hep C clinic. We have about 90 patient slots per work for new and follow-up patients. We are plagued by multiple issues that limit curative treatment and lack of medications as we treat mostly Medicaid is only one of them. Other issues include active substance users and alcoholics who have limited rehab options, patients with comorbid psych issues and few options for treatment, patients with high no show rates (as high as 50+%), and transportation issues that limit

	attendance. Increased substance abuse treatment, transportation, social workers and patient navigation would really improve capacity and distribution.
5. How should a subscription model account for the fact that a small percentage of patients may fail initial treatment or be reinfected?	
Answer 5:	Reinfection is always possible but treating people with ongoing risk factors for transmission can flatten or cause the epidemic curve to descend resulting in less infections of others. I do not think patient's who adhere to therapy but fail due to clear should have treatment withheld.
6. How many patients do you anticipate being able to access curative treatment over this timeframe, categorized by population? Do you anticipate this to change by year, and if so, by how much?	
Answer 6:	I am not sure, this is hard to estimate as many patients we see currently we are unable to treat. The clinic I co-direct at the ID Center at UMC has a booming Hep C clinic. We have about 90 patient slots per work for new and follow-up patients. We are plagued by multiple issues that limit curative treatment and lack of medications as we treat mostly Medicaid is only one of them. Other issues include active substance users and alcoholics who have limited rehab options, patients with comorbid psych issues and few options for treatment, patients with high no show rates (as high as 50+%), and transportation issues that limit attendance. Increased substance abuse treatment, transportation, social workers and patient navigation would really improve capacity.
7. For the managed Medicaid population, should this program be "carved out?"	
Answer 7	the less we have to deal with managed Medicaid the better. Hours per week are wasted arguing with the insurance companies and completing peer to peers with non-peers.
8. How should the DAAs be stocked, restocked and dispensed in a subscription model? What is the role of community pharmacies?	
Answer 8:	As long as they can be accessed quickly it does not matter to be where they are stored.
9. What legal or regulatory issues does a subscription model raise and how can they be addressed through federal waivers (e.g., Medicaid Section 1115 waiver), pilot programs (e.g., those offered under the Center for Medicare and Medicaid Innovation), or regulatory guidance (e.g., from CMS or OIG)? Please be specific.	
Answer 9:	not sure
10. What are key aspects of an elimination campaign that should complement a subscription model approach to antiviral medication?	
Answer 10:	
11. Is there anything else you would like to share with the Department related to our consideration of a subscription model?	
Answer 11:	Please be sure to have the additional services needed to maximize the capacity and effectiveness of treatment, such as social works, substance abuse/alcohol treatment, patient navigation etc that are other barriers to care.

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1. Do you support a subscription payment model that tackles the public health crisis of Hepatitis C in Louisiana? Why or why not?

Answer 1: We at CrescentCare support innovative ways to treat HCV, so yes, we support subscription as one option to treat the large number of Medicaid recipients currently unable to access a cure for Hepatitis C.

2. In addition to the Medicaid and corrections population, Louisiana is interested in exploring coverage for the uninsured as part of an elimination strategy. How could this strategy be expanded to cover some or all of the uninsured?

Answer 2: We would welcome this, yet, we would want to know how Louisiana would do this in conjunction with the patient assistance programs. Currently, the major pharmaceutical companies supplying DAAs for HCV have a relatively high-income threshold for approving their products for HCV treatment. We've had reasonable success securing Medications for uninsured Louisianans and Mississippi residents referred here for treatment. From our New Orleans Syringe Access Program (NOSAP) this year, 43%, are uninsured; 46% of those who are homeless or unstably housed also reported not having insurance. A two-fold strategy of informing uninsured Louisianans of their potential benefits while working with programs and agencies that directly serve affected populations (syringe access, recovery/ Rehab services, reentry programs) of the subscription model and how to access it would provide the greatest reach into communities in need of HCV treatment would possibly benefit some of the populations who are marginalized or not as empowered to seek treatment and go through the process of patient assistance.

3. Under a subscription model, what strategies should the state use to identify people with Hepatitis C infection who are unaware of their infection? What should be done to increase awareness of Hep C and options for treatment?

Answer 3: A) Marketing: using Community Health Centers (FQHCs) and Ryan White-funded agencies, with directed, consistent messaging about HCV diagnosis, linkage, treatment, and cure. A similar program was done with HIV (retention) and was shown to be very effective at a minimal cost. We would also encourage the state to consider public service campaigns similar to the NOLA HealthLink model, with signs, locations (for testing and treatment), and web-information about HCV linkage, treatment, and cure. B) Testing: increasing funding and infrastructure support for agencies that provide testing and treatment services should be a first step in funneling eligible clients to treatment through this program Providing training and test kits so people can choose to receive a HCV rapid test wherever they may receive an HIV or Syphilis test. The Department of Health should continue to expand testing options to include a confirmatory/RNA test for expedited linkage to a provider who can prescribe appropriate HCV treatment. 3) Rapid linkage and treatment. At CrescentCare we implemented an immediate linkage and treatment program for HIV 12/2016. While there are some differences in diagnosis and initiation of HCV DAAs, we've been able to suppress over 200 clients with HIV in less than 30 days, and

92% are retained in care. We feel the model of "warm handoff" using a navigator (with cell phones employing 2-way texting) who is empowered to schedule visits & health center infrastructure which can support these urgent visits. We would also encourage funding for transportation to ensure clients are able to make their appointments. The cost for most would be minimal, given the (often) relatively few numbers of visits required for treatment and cure of HCV with current regimens. FQHCs and Ryan White programs are ideal for programs like this as they are seeing high volumes of Medicaid clients already and are anxious to help them with chronic medical conditions, such as HCV and HIV. Achieving buy-in from these health centers (which we feel could be done quite easily if medications were available) will be paramount to success of such a program.

4. How should Louisiana create the clinical capacity for distribution and treatment of DAAs for Hepatitis C?

Answer 4: We would envision a spoke-and-hub model with possible involvement of telemedicine for clinics/health centers located at a distance from HCV-capable providers. The spoke would be Ryan White -affiliated or ID-affiliated FQHCs and health centers, who often have providers more comfortable with treatment and management of HCV. These 'spoke' providers could work in conjunction with the hubs for lab and medical follow-up after initial consultation, evaluation, and initiation of therapy, to limit transportation barriers and costs associated with going to referral centers. Similarly, telemedicine could also bridge this gap by connecting clients at hub centers to a spoke with HCV-trained providers.

5. How should a subscription model account for the fact that a small percentage of patients may fail initial treatment or be reinfected?

Answer 5: We feel this should be accounted for on two levels: 1) Medications - we feel it is essential for people who fail treatment (do not achieve SVR) or are re-infected to receive treatment, otherwise efforts to end HCV in our state will not succeed. Currently there are two regimens (across drug manufacturers) which are indicated for those who don't achieve SVR. We would hope that these (along with therapies which might be released in the coming years) would be available to clients in need of them. 2) Harm reduction, decriminalization of drug paraphernalia, increase in access to clean needles, health education (for injecting) and reducing stigma are paramount to prevent re-infection with HCV, along with treating the majority of those infected (reducing community viral load).

6. How many patients do you anticipate being able to access curative treatment over this timeframe, categorized by population? Do you anticipate this to change by year, and if so, by how much?

Answer 6: We would like to see the (estimated) >70,000 individuals living with HCV treated and cured. We realize this will take time, and would foresee, if the correct infrastructure were in place, a ramp-up period in the first year, a very busy years 2-3, and then a decline in numbers in years 3-5.

7. For the managed Medicaid population, should this program be "carved out?"

Answer 7 We feel all individuals with Medicaid should be treated- regardless of plan.

8. How should the DAAs be stocked, restocked and dispensed in a subscription model? What is the role of community pharmacies?

Answer 8: We would like to see this program run through several well-vetted specialty pharmacies across the state, which have proven reliable for inventory (calculations for stocking, re-stocking) & have the ability to mail medications to patients. This would offer more control on the program. We would like to see an option for exceptions for those who do not have access to a mailbox whereby medications could be mailed to community clinics or even community pharmacies for those.

9. What legal or regulatory issues does a subscription model raise and how can they be addressed through federal waivers (e.g., Medicaid Section 1115 waiver), pilot programs (e.g., those offered under the Center for Medicare and Medicaid Innovation), or regulatory guidance (e.g., from CMS or OIG)? Please be specific.

Answer 9: We do not have comments for this question at this time.

10. What are key aspects of an elimination campaign that should complement a subscription model approach to antiviral medication?

Answer 10: Syringe access, harm reduction training (clinics, community health workers, and clients), enhanced availability of co-located services (MAT - Suboxone/Vivitrol/Methadone + HCV treatment + syringe & needle access), case management and housing options for those living with HCV, transportation access, and navigation are key to success of an elimination campaign for HCV.

11. Is there anything else you would like to share with the Department related to our consideration of a subscription model?

Answer 11: It is our strong commitment to follow national guidelines which state all people living with Hepatitis C should have access to curative treatment.

If the commenter is a pharmaceutical company that manufactures a Hepatitis C treatment, we request attention to these questions in addition to the previous questions:

12. Is your company willing to consider a subscription model as outlined above?

Answer 12: Yes

13. Are there alternative cost-neutral or cost-saving models you propose to achieve Louisiana's goal?

Answer 13: No

14. What length of time would be appropriate for a subscription model contract for Hepatitis C treatment?

Answer 14: 5 years

15. What special payment considerations (e.g., use of the 340B program) should be considered to ensure access to curative treatment for each population?

Answer 15: We do not have a comment for this right now.

16. In what ways would your company be able to support the public health and clinical infrastructure that will maximize access to curative treatment?

Answer 16: CrescentCare has over 10 providers who are trained experts in the field in management of HCV. More importantly, we have the proven testing infrastructure (providing over 12,000 HIV tests in New Orleans in the last year), we house the New Orleans Syringe and Needle Access program (providing over 600,000 clean needles for patients last year), HCV testing (rapid and diagnostic) at multiple sites, navigation, case management, and health education. We recently were awarded a large SAMSHA grant and are providing addiction services (both therapy and MAT). We are moving to a more centralized location at 1631 Elysian Fields where more clients will have access to co-located services.

17. Are there any other important considerations relevant to your potential participation in a subscription model?

Answer 17: We have the infrastructure to support a robust number of patients directly + the telemedicine equipment to support treatment in other areas of the state who might not have access to services.

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Phone	2025406512

1. Do you support a subscription payment model that tackles the public health crisis of Hepatitis C in Louisiana? Why or why not?

Answer 1:	<p>The Pew Charitable Trusts (Pew) is pleased to offer comments on the Louisiana Department of Health Request for Information (RFI) on Subscription Payment Models. Pew is an independent, nonpartisan research and public policy organization dedicated to serving the American public. Our drug spending research initiative(1) is focused on identifying policies that would allow public programs to better manage spending on pharmaceuticals while ensuring that patients have access to the drugs that they need. Pew commends the Louisiana Department of Health for its goal to eradicate Hepatitis C (HCV). In particular, we applaud the efforts to extend curative HCV treatment to incarcerated persons and the uninsured, two populations that historically have faced significant barriers in accessing treatment. In this response, we focus our comments on how Louisiana can access discounted pricing for HCV Direct-Acting Antiviral (DAA) therapies for these populations, regardless of whether the discounted pricing is achieved through a subscription model or another approach. We also consider how Louisiana can leverage HCV DAA negotiations to reduce HIV treatment costs for incarcerated populations and how Louisiana can simultaneously build a framework to reduce overall drug costs in the correctional system. These comments do not address potential sources of funding to cover the costs care associated with diagnosing and treating HCV and other conditions. 1) The Pew Charitable Trusts. "Drug Spending Research Initiative," http://www.pewtrusts.org/en/projects/drug-spending-research-initiative.</p>
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2. In addition to the Medicaid and corrections population, Louisiana is interested in exploring coverage for the uninsured as part of an elimination strategy. How could this strategy be expanded to cover some or all of the uninsured?

Answer 2:	<p>Pew commends Louisiana for including correctional and uninsured populations in its elimination strategy, as these two populations are generally unable to access the discounted drug prices available under the Medicaid program. Pew has published an analysis, including model administrative or legislative text, detailing how states can access discounted drug prices for correctional populations through discounted manufacturer sales to a designated 340B-eligible provider, such as an academic hospital affiliated with a public medical school or a network of community health centers; this policy could also be used to allow uninsured patients to access HCV DAA treatments at discounted prices. The Medicaid Drug Rebate Program (MDRP) Best Price requirement has been cited as a barrier to extending discounted drug pricing to incarcerated and uninsured populations.(2) Under the Medicaid statute, the lowest price a drug manufacturer offers to certain purchasers on any product</p>
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must also be made available to all Medicaid programs. In addition, the manufacturer is required to make that discounted price available to all entities participating in the 340B Drug Discount Program, a federal program which provides discounts to hospitals and clinics that meet federal standards for serving low-income or uninsured patients.(3) If a manufacturer were to sell deeply discounted HCV DAA treatments directly to a state department of corrections, an individual correctional facility or a clinic for uninsured patients, that could trigger the best price requirement, discouraging the manufacturer from offering these discounts. The Medicaid best price provision of the law has a variety of carveouts that allow manufacturers to offer discounts to certain providers without establishing a lower Medicaid price. One of these carveouts exempts all discounts given to 340B covered entities, regardless of whether the discount is required under the 340B program or whether the discount is voluntary.(4) This is an important distinction – while patients must meet certain requirements to be entitled to the mandatory 340B discount, they do not need to meet these requirements to receive a voluntary manufacturer discount via a 340B entity. Manufacturers may voluntarily provide discounts to these hospitals outside of the 340B program without triggering best price and without requiring incarcerated adults to be transported to the hospital.(5) If manufacturers provided a voluntary discount to a designated 340B academic hospital or hospitals for incarcerated adults, correctional facilities would not have to transport incarcerated adults to the 340B hospital to receive discounts, a logistically challenging and costly process. Instead, correctional facilities could use telemedicine or have physicians from the 340B hospital visit the correctional facility for diagnosis; prescriptions would be mailed or couriered from the 340B hospital's pharmacy and the correctional facility or department would reimburse the 340B hospital. Because voluntary discounts to 340B hospitals are exempted from best price regardless of whether the patient meets 340B eligibility criteria, manufacturers would not face any best price liability under this arrangement. This model would also allow uninsured patients to access discounted HCV DAA pricing without having to meet the 340B patient eligibility criteria. Uninsured patients could be seen at the designated 340B hospital for HCV diagnosis and treatment, or could be treated by another local health care provider, such as at a community health center, in consultation with providers at the 340B hospital; the uninsured patient's medication would be distributed from the stock of discounted HCV DAA treatments maintained by the 340B hospital under the program. References (2) Ted Alcorn, "Hepatitis C Drugs Save Lives, but Sick Prisoners Aren't Getting Them," The New York Times, March 15, 2018, <https://www.nytimes.com/2018/03/15/us/hepatitis-c-drugs-prisons.html>. According to the article, "Like other drugmakers, Gilead promises its best price to state Medicaid programs, the Department of Veterans Affairs, and certain hospitals. If the company lowered the price for prisons, Mr. Alton said, it would have to further reduce it for these other entities. Giving prison health systems access to the same discounted price would require an act of Congress." (3) 42 U.S.C. § 1396r-8(c)(1)(C). (4) 42 C.F.R. § 447.505(c)(2). For a discussion of this policy, see 81 Fed. Reg. 5170, 5256-7. (5) Centers for Medicare & Medicaid Services, "Covered Outpatient Drug Final Rule With Comment (CMS-2345-FC): Frequently Asked Questions" (July 6, 2016), <https://www.medicare.gov/federal-policy-guidance/downloads/faq070616.pdf>.

3. Under a subscription model, what strategies should the state use to identify people with Hepatitis C infection who are unaware of their infection? What should be done to increase awareness of Hep C and options for treatment?

Answer 3:

4. How should Louisiana create the clinical capacity for distribution and treatment of DAAs for Hepatitis C?

Answer 4: Both academic hospitals affiliated with public medical schools and community health center networks may be candidates to manage the treatment of HCV and distribution of HCV DAAs under a statewide discounted drug acquisition program. These entities have clinical experience in HCV treatment, and in most cases they qualify for and participate in the 340B program. While Pew has not analyzed the specific organizational and clinical capacity of these providers in Louisiana, we provide general comments on how either provider could administer such a program. In addition, in 2016 the Louisiana Department of Public Safety and Corrections reported to Pew researchers that it had contracted with a 340B provider to provide specialty care for some incarcerated persons, which allowed the department to access discounts for prescriptions related to that care.(6) The voluntary discount model discussed here is distinct from that approach. Under an academic medical center model, the discounted HCV DAA distribution structure could resemble a hub-and-spoke system, with a centralized process for determining patient eligibility and drug delivery. In this model, the state would negotiate a discounted price on the medication with the manufacturer. The manufacturer would sell drugs to the 340B-eligible academic medical center at the negotiated price, and the academic medical center would maintain the drugs in a separate inventory. 340B-eligible hospitals generally already maintain separate inventories for drugs purchased under the 340B program and non-340B purchases, as not all patients are eligible to receive 340B-purchased drugs.(7) The academic medical center would leverage its existing inventory model to incorporate purchases under the discounted HCV DAA program. When a patient is determined to be eligible for the program under the state's criteria, the academic medical center would enroll the patient in the program and provide a variety of clinical and adherence management services, including distribution of the HCV DAA to the patient from its central pharmacy; clinical services could be provided either in-person or through telemedicine, which could facilitate treatment of incarcerated persons. The state would make a capitated payment to the academic medical center for the entire care package provided, acting entirely as an insurer and not a purchaser of the HCV DAA. Under a community health center (CHC) network model, a statewide CHC network would have a contract with the state to administer the program. The CHC would leverage its existing 340B inventory management framework to segregate discounted HCV DAAs purchased under this program from other inventory, distributing them only to eligible patients. If patients eligible for the discounted HCV DAA program, as defined by the state, are widely distributed across the state in areas served by the CHC network, this model may present administrative efficiencies compared to a hub-and-spoke centralized model. CHCs could see eligible patients directly, linking them to any other needed health or social services. As in the academic medical center model, the state would make a capitated payment to the CHC for the entire care package provided, acting entirely as an insurer and not a purchaser of the HCV DAA. Because this discount model relies on the 340B eligibility of the purchasing agent, whether an academic medical center or a CHC, to avoid triggering best price, it is essential that any reimbursement for the discounted HCV DAA from the state must not be considered a best price-eligible transaction. If community pharmacies are involved in distributing discounted HCV DAAs, the state must ensure that these transactions be exempt from best price; registering designated community pharmacies as contract pharmacies (8) of the 340B entity selected to manage the discounted HCV DAA purchasing would facilitate community pharmacy participation in the program, as drugs distributed by these community pharmacies would still be considered under the auspices of the selected 340B entity and therefore would not trigger the best price provision. References (6) The Pew Charitable Trusts, "Pharmaceuticals in State Prisons" (December 2017), <http://www.pewtrusts.org/~media/assets/2017/12/pharmaceuticals-in-state-prisons.pdf>. (7) Wright, S. "Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431," Department of Health

	and Human Services Office of Inspector General (Feb. 4, 2014). https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf . (discussing various 340B inventory management systems). (8) Health Resources and Services Administration Office of Pharmacy Affairs. "Contract Pharmacy Services" (May 2018). https://www.hrsa.gov/opa/implementation/contract/index.html .
5. How should a subscription model account for the fact that a small percentage of patients may fail initial treatment or be reinfectd?	
Answer 5:	
6. How many patients do you anticipate being able to access curative treatment over this timeframe, categorized by population? Do you anticipate this to change by year, and if so, by how much?	
Answer 6:	
7. For the managed Medicaid population, should this program be "carved out?"	
Answer 7	
8. How should the DAAs be stocked, restocked and dispensed in a subscription model? What is the role of community pharmacies?	
Answer 8:	
9. What legal or regulatory issues does a subscription model raise and how can they be addressed through federal waivers (e.g., Medicaid Section 1115 waiver), pilot programs (e.g., those offered under the Center for Medicare and Medicaid Innovation), or regulatory guidance (e.g., from CMS or OIG)? Please be specific.	
Answer 9:	While Pew cannot provide a legal assessment of a specific program, we note that the method of extending discounts to correctional and uninsured populations described in these comments is consistent with existing federal regulations and statutes and would be unlikely to require any waivers or additional guidance. A manufacturer may inform the Centers for Medicare & Medicaid Services (CMS) through a "reasonable assumptions" letter of the arrangement and the manufacturer's assessment that any sales under this program would not trigger the Medicaid best price provision;(9) this allows CMS an opportunity to respond to the manufacturer's assumptions if CMS does not agree with them. Reference (9) Department of Health and Human Services Office of Inspector General. "Reasonable Assumptions in Manufacturer AMP Reporting" (2017). https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000216.asp . See also 42 CFR § 447.510(f)(1)(i) (Requirements for manufacturers, "The records must include these data and any other materials from which the calculations of the AMP, the best price, customary prompt pay discounts, and nominal prices are derived, including a record of any assumptions made in the calculations.").
10. What are key aspects of an elimination campaign that should complement a subscription model approach to antiviral medication?	
Answer 10:	
11. Is there anything else you would like to share with the Department related to our consideration of a subscription model?	
Answer 11:	As Louisiana builds the infrastructure to enable correctional facilities to access discounted HCV DAA pricing, it should consider how this infrastructure could be leveraged to ensure correctional facilities and uninsured patients are able to access other drugs at discounted prices. Drug spending has an outsized

impact on correctional healthcare budgets: of states that report drug spending, the majority spend over 15% of their correctional health care budget on drugs, with some states spending up to 32%.(10) Many incarcerated persons with HCV may also be living with HIV;(11) since many HIV treatments are produced by the same manufacturers as HCV DAAs, Louisiana may consider simultaneously negotiating discounts for HCV DAAs and HIV treatments for incarcerated populations. In selecting an academic medical center or CHC to administer the discounted HCV DAA program for the correctional population, Louisiana should consider the entity's ability to administer a larger discounted drug program for the correctional population, such as the proposal to extend Medicaid discounts to correctional populations as a condition for a manufacturer's inclusion on the Medicaid Preferred Drug List. We appreciate the opportunity to respond to this RFI and commend the state for its attention to the Hepatitis C public health crisis in Louisiana. Should you have any further questions, please contact me at ireynolds@pewtrusts.org. Sincerely, Ian Reynolds Manager, Drug Spending Research Initiative The Pew Charitable Trusts 202.540.6512 References (10) The Pew Charitable Trusts, "Pharmaceuticals in State Prisons" (December 2017), <http://www.pewtrusts.org/~media/assets/2017/12/pharmaceuticals-in-state-prisons.pdf>. (11) Hennessey KA et al. Prevalence of infection with hepatitis B and C viruses and coinfection with HIV in three jails: a case for viral hepatitis prevention in jails in the United States, in Journal of Urban Health, Vol. 86, pp. 93–105, 2008.



Re: Response to Louisiana's Request for Information on Subscription Payment Models

The AIDS Institute, a nonpartisan, nonprofit organization focused on ensuring access to treatment for individuals living with chronic conditions such as hepatitis and HIV, appreciates the opportunity to respond to the Louisiana Department of Health's *Request for Information on Subscription Payment Models*. We applaud the state's desire to increase HCV treatment rates among the Medicaid, corrections, and uninsured populations in order to cure people in the state of this potential deadly infectious disease.

The AIDS Institute has previously submitted comments to the Louisiana Department of Health in a letter dated June 7, 2017 titled *Comments on Louisiana's Proposed Recommendations for Treating Hepatitis C* (see attachment). Many of our comments and recommendations pertaining to legal requirements contained in the Medicaid program, the public health value of curing people living with hepatitis C, along with the actual budget impact of expanding treatment, and how the state can use existing programs to increase treatment among uninsured individuals remains relevant.

Current Medicaid Obligation to Expand Treatment Access

We continue to urge Louisiana to increase access to hepatitis C (HCV) treatment **now** since the state is legally required to provide medications to its Medicaid recipients in accordance with current Medicaid rebate provisions and the FDA label for the approved treatments. The continued argument that the state's budget is unable to handle an increase in treatment rates through conventional means without cutting other services is not a reason to ignore the law and is discriminatory against people living with HCV.

It also ignores the fact that treatment costs are now lower than ever, and that the state can negotiate additional discounts with manufacturers for treating Medicaid recipients and those in the correctional system, as other states already do. For example, earlier this year, the State of Florida announced a multi-year "cost-saving agreement" with a manufacturer that allows treatment of the state's inmates living with HCV. The agreement came about after the state sent a letter to manufacturers asking for "innovative solutions" and to partner with the state. We urge Louisiana to do something similar in respect to its prison population.

In our previous letter, we commented on analysis conducted for the Louisiana Department of Health and concluded that the average cost of the *state's share* would only be \$8,280 per patient receiving HCV treatment through Medicaid. This is due to the fact that Medicaid is a joint federal/state program and the federal government would pick up most of the costs, particularly since Louisiana



is now a Medicaid expansion state. Competition has been steadily increasing since the first HCV treatment came onto the market in 2013, and prices have significantly dropped since that time, even since the state conducted their own cost analysis. In fact, earlier this year one manufacturer announced a reduction in the cost of their treatment at a list price 17 percent lower than the previously cheapest treatment. Given the automatic rebates state Medicaid programs receive on FDA-approved drugs, plus the state's ability to negotiate additional discounts, it is likely that the state can treat Medicaid recipients at an even lower cost than the previously cited \$8,280 amount. Treatment cost should no longer be an excuse to restrict access to treatment particularly since treatment costs can be lowered through means already at Louisiana's disposal.

As we addressed in our June 2017 letter, Louisiana is not complying with Medicaid law or its constitutional duty to provide adequate and timely health care to its correctional population. Currently, Louisiana Medicaid restricts access to HCV treatment to those with a Fibrosis Score of F3 or higher and have attested that they have abstained from substance use. While we commend Louisiana for recently removing prescriber requirements and for loosening sobriety requirements, these changes are far from what is legally required. The people of Louisiana living with HCV deserve to be treated and cured now. We are disappointed that last year the program was only able to treat 384 people of the approximately 30,000 Medicaid recipients living with HCV in the state. Even with the loosening and removal of some of the treatment restrictions in Medicaid, the remaining Fibrosis Score restrictions violate current Medicaid law, which forbids states from restricting access to medical treatment.

Multiple states have had litigation filed against their Medicaid programs for failing to treat people living with HCV in a timely manner. Many of those cases have either resulted in rulings that require the state to cover treatment, or the states have voluntarily agreed to increase access to treatment prior to a final ruling. In the past 13 months, 17 states have completely removed Fibrosis Score restrictions from their Medicaid programs, making Louisiana one of only 10 states to require a Fibrosis Score of F3 or higher to receive treatment.

Pursuing a subscription payment model will continue to delay access to treatment for a lengthy period of time for those living with HCV. While the state is now seeking comments on its *Request for Information*, it will likely lead to a *Request for Proposals* if the state decides to pursue this model. If a manufacturer is interested in this scenario, the state would have to negotiate costs and conditions. Eventually, if Louisiana seeks changes to its Medicaid program, it would have to seek approval from the federal government, which will take additional time. Each of these steps would require significant time to complete. During all this time, Louisiana should be treating and curing its citizens, something it is legally obligated to do now.

We would be interested in learning what authorities Louisiana is acting under to make these changes to the Medicaid system and to, at the same time, provide



treatment to its prison population and the uninsured, who are outside the Medicaid program.

Considerations for Subscription Payment Model

Should Louisiana decide to pursue a subscription payment model, there are several items that we urge the state to consider. Any program should be implemented for a multi-year period that allows ample time for those living the HCV in the state to be identified, tested, linked to care, treated, and cured.

One of the most robust HCV treatment efforts currently happening in the U.S. is by the Department of Veteran Affairs (VA), which is attempting to eliminate HCV within the veteran population. Even with a robust testing and linkage to care effort in place, the VA estimated it will have only treated 80 percent of their HCV population in the first four years of the program. Ample time would be necessary in order for Louisiana to successfully treat a large portion of their target treatment population. Additionally, we urge the state to follow the VA's example and invest resources into building out their testing, linkage to care, and treatment infrastructure. Louisiana will not be successful in treating a large portion of its population living with HCV unless it is able to identify, test, and link those individuals to care. That requires increased public education, additional testing venues, and providers who are familiar with providing treatment. Having access to an affordable treatment is only one aspect of a robust and successful treatment program, and we encourage Louisiana to make investments in the other aspects necessary for a successful program.

We again applaud Louisiana's effort to increase the treatment and cure rates of people living with HCV in the state and urge Louisiana to utilize the options already available to increase treatment access and to implement them in a timely manner. Thank you.

Sincerely,
Carl Schmid
Deputy Executive Director
Attachment



Re: Comments on Louisiana's Proposed Recommendations for Treating Hepatitis C

The AIDS Institute is encouraged that Louisiana is taking strides to treat its uninsured population living with hepatitis C (HCV), particularly its Medicaid beneficiaries, and is pleased to offer comments on *Hepatitis C in Louisiana: Recommendations on Drug Availability*.

HCV is a serious deadly infectious disease with treatment available that leads to a cure. Access to these curative medications is necessary to avoid future related health problems such as liver disease, cirrhosis, liver cancer, and to decrease future infections. Given that treatment is so necessary and in almost all instances leads to a cure, we believe Louisiana's current Medicaid policy, which restricts treatment until patients have severe liver damage, is unacceptable and violates current Medicaid law. We are pleased that you are taking steps to change it so that more people in Louisiana will be able to take advantage of the curative medications. We realize that Louisiana is only in the position to make these changes possible because it has expanded Medicaid, which is a benefit to an estimated 428,000 low-income people in the State. However, we believe that some of the assumptions Louisiana is making that has led you to propose extraordinary actions are flawed.

The analysis that Louisiana conducted fails to consider 1) future cost-savings that the state Medicaid program will realize by curing people with HCV; 2) the time frame that Medicaid beneficiaries with HCV will seek treatment; and 3) other payers, such as the Ryan White HIV/AIDS Program, that can assist with uninsured people who are co-infected with HIV.

While we realize that purchasing HCV curative medications will impact Louisiana's Medicaid budget, we disagree that it is impossible to address this challenge through conventional approaches to drug pricing. This is due to the fact that the price of the drug has been dramatically discounted and total expenditures will be spread out over several years. Other states are successfully treating their citizens in compliance with current Medicaid law, and Louisiana should as well.

Currently, Louisiana Medicaid's policy is to restrict access to HCV treatment to only those with a Fibrosis Score of F3 or higher, who have abstained from substance use for 12 months or longer, and have received their prescription from a specialist. These restrictions violate current Medicaid law, which forbids states from restricting access to medical treatment on the basis of the treatment's cost. The restrictions are also contrary to the American Association for the Study of Liver Diseases' (AASLD) treatment guidelines that encourage treatment of nearly all patients diagnosed with HCV--regardless of Fibrosis Score or abstinence length. Additionally, the National Academies of Science, Engineering, and Medicine (NASEM) recently recommended that health plans,



including Medicaid, “remove restrictions that are not medically indicated and offer direct-acting antivirals to all chronic hepatitis C patients” in order to make eliminating viral hepatitis as a public health threat in the United States a possibility. Withholding treatment and forcing patients to wait until their liver is severely damaged or until they have reached a certain length of abstinence causes undue harm. This is a policy that must be changed.

While headlines often focus on the list price of the HCV curative medications, according to analysis conducted for the Louisiana Department of Health, the average cost to the state’s Medicaid program would **only be \$8,280 per patient receiving HCV treatment**. This reflects the significant rebates and discounts that pharmaceutical manufacturers are offering and the fact that the federal government carries the largest share of the costs in the Medicaid program.

According to our calculations, treating the 20,000 Medicaid recipients living with HCV at \$8,280 per treatment would cost the state \$165.6 million. The recommendations focus heavily on the estimated \$765 million cost to treat the Medicaid *and* uninsured populations living with HCV, but more than half of the target population can be treated for a small portion of that cost. Because treatment results in a cure nearly 100 percent of the time, this would be a one-time cost and unlike so many other Medicaid costs, not reoccurring.

We fail to understand why Louisiana is singling out and only restricting HCV treatment. In 2015, Louisiana spent \$8.3 billion on its entire Medicaid program and of that amount, only 4.8 percent, or \$398 million, on prescription medications. Therefore, when considering the State’s overall Medicaid expenditures, HCV treatment would not be a significant cost. We believe it is unfair to present to policy makers that Louisiana must make a choice between funding schools, public services and infrastructure programs or HCV curative medications.

While The AIDS Institute would never suggest a reduction in Louisiana Medicaid spending for HIV medications, we note that the state Medicaid program spent \$48 million on HIV treatments in 2015. Unlike HCV, HIV is an incurable chronic condition, so the costs are incurred year after year. With HCV, all the costs would be over a short duration until a patient is cured. Louisiana Medicaid also spends billions of dollars treating other chronic conditions and other Medicaid services that bear a much greater share of the Medicaid budget. Instead, Louisiana continues to focus on HCV treatment.

We also take issue with the assumption that all HCV treatment costs will be borne in a single year. It is highly unlikely that all of the estimated 20,000 Medicaid recipients living with HCV will receive treatment in the first year of increased access. More than 50 percent of people living with HCV do not know they are infected, so they do not know they even need to seek treatment.



Treatment rates will be spread across multiple years as individuals gradually learn they have the disease. States that currently have no or few treatment restrictions in Medicaid have not had their entire treatment-eligible population come in for treatment in a single year. In fact, the Department of Veterans Affairs (VA) has opened access to HCV treatment and actively pursued connecting veterans living with HCV to treatment. They have not been able to treat all of their HCV patients in one year. The VA currently estimates it will take four years to treat 80 percent of their HCV population. The \$165.6 million estimated to treat the 20,000 Louisiana Medicaid recipients living with HCV would be spread across multiple years, which means the expenditures per year will only be a fraction of the assumed total.

We believe that future cost-savings to the Medicaid program by treating and curing people with HCV should also be considered as part of Louisiana's cost calculations. Numerous studies have found that it is cost-effective to treat HCV early because untreated HCV can lead to liver disease, cirrhosis, liver cancer, and liver transplants. All of these require long-term care at high costs. Louisiana's Medicaid program would save money in the long-term by treating HCV early and robustly.

Additionally, the fact that approximately five percent of people living with HCV are also co-infected with HIV is also not considered. Some of these individuals who are co-infected can be treated through the Ryan White HIV/AIDS Program, lowering the state's overall treatment costs.

The AIDS Institute recommends that the Louisiana Department of Health follow current Medicaid law, AASLD guidelines, and NASEM recommendations and **remove access restrictions to HCV treatment to allow all Medicaid recipients diagnosed with HCV to receive treatment.** Opening up treatment access will result in cost savings in the long-run. Short-term costs would be spread out over multiple years, keeping them manageable without drastic adjustments to the existing budget. We also recommend the state **work to connect individuals co-infected with HCV and HIV to the Ryan White HIV/AIDS Program to receive treatment.**

By increasing access and actively working to connect individuals living with HCV to one-time curative treatment, it is possible to treat a large portion of Louisiana's Medicaid population living with HCV through the existing mechanisms of accessing medications. The price of the medications has dropped precipitously, Louisiana's share would only be slightly over \$8,000 per cured patient, and it would be spent over several years. We urge the Louisiana Department of Health to reject the proposed recommendations in *Hepatitis C in Louisiana: Recommendations on Drug Availability* and look to conventional, proven solutions to combatting this serious public health threat.



Thank you.

Sincerely,

Carl Schmid

Deputy Executive Director



Dear Mr. Croughan:

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), we appreciate the opportunity to respond to the Request for Information on Subscription Payment Models as the state seeks solutions to providing curative Hepatitis C medicines to Louisianans in need of treatment. We are submitting this letter in addition to the comments submitted via the website.

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that allow patients to lead longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than \$600 billion in the search for new treatments and cures, including an estimated \$71.4 billion in 2017 alone. PhRMA has a long-standing goal of promoting access to quality care and we applaud recent steps the state of Louisiana has taken to increase patient access to Hepatitis C medications, such as the elimination of the prescriber specialty requirement in Medicaid and making Direct Antiviral Agents (DAAs) more readily available to Medicaid beneficiaries with comorbidities and behavioral disorders.¹

We support increased prescription drug access through voluntary alternative financing arrangements with manufacturers. As the state analyzes the potential for new financing arrangements, we recommend the state consider the challenges of new arrangements that cross various types of patients with coverage through government programs, employer or commercial insurance, or the uninsured.

Innovation leads to Cures

New curative therapies are changing the trajectory of the lives of people living with Hepatitis C. Just five years ago, the only available treatment for Hepatitis C was associated with debilitating flu-like side effects and cured just half of patients, leaving those who failed to respond to treatment without an alternative option. Now, with cure rates of over 95% for previously untreated patients, with minimal side effects, there are potential savings of over \$800 million accruing to Medicaid each year post-treatment.²

¹ Louisiana Fee for Service (FFS) Medicaid and Managed Care Organizations (MCOs) Hepatitis C Virus (HCV) Direct-Acting Antiviral (DAA) Agents

Clinical Prior and Pre-Authorization Criteria Revision, available at <http://ldh.la.gov/index.cfm/page/3046>

M. Christopher Roebuck, Joshua Lieberman Burden of Illness of Chronic Hepatitis C in Medicaid, RxEconomics



Within a year of the introduction of the first breakthrough hepatitis C treatment, there were multiple competitors in the market, which enabled payers to negotiate deep discounts for these medicines in exchange for favorable formulary placement. In fact, competition drove rebates ranging from about 22% in 2014³ to discounts ranging from about 40-65% today. Moreover, owing to the success of this competitive market dynamic, evidence suggests negotiated prices in the US are typically lower than in most European countries.⁴ What's truly remarkable, however, is that researchers now project that hepatitis C will be a rare disease by 2036.⁵

Alternative Financing Mechanisms

We recognize states' needs to better predict and plan for spending, while providing quality care and access to the latest innovative therapies. As such, PhRMA supports state efforts to explore voluntary alternative financing arrangements, such as a subscription payment model. In the Medicaid program, such an arrangement could be structured as a CMS-approved supplemental rebate, with a state potentially paying a manufacturer an annual fixed fee for unlimited utilization of a manufacturer's drug in the Medicaid program. In designing such a program, it would be important to consider payment and reimbursement barriers that exist within the current supply chain, statutory Medicaid rebate obligations, and considerations for how it could best serve the needs of Medicaid beneficiaries.

As Louisiana works to implement any voluntary alternative financing arrangement, PhRMA urges the state to consider patients who are currently stable on a prescription medicine and to develop processes to ensure these patients can continue with their current prescription drug therapy without interruption. In addition, PhRMA encourages the state to develop easily accessible and transparent prior authorization and appeals processes for both prescribers and patients who need access to a drug that may be non-preferred under an alternative financing arrangement.

Coverage of Diverse Populations

States face a considerable challenge in ensuring that residents have access to quality, affordable health care. PhRMA remains committed to ensuring accessibility to needed medicines for Medicaid beneficiaries, and our member companies have held to the statutory bargain under which states receive rebates in exchange for guaranteed coverage, to ensure that every patient, in consultation with his or her physician, has access to therapies that can improve quality of life. However, we also appreciate the need that exists in corrections settings and among the uninsured. Curing a patient's Hepatitis C is dependent on having stable access to health care coverage to provide for the complete course of treatment, which lasts an average of 12 to 24 weeks.

³ Silverman, "The Hepatitis C Scorecard: Gilead is Trouncing AbbVie, but at a Price," Wall Street Journal, Feb. 12, 2015,

<http://blogs.wsj.com/pharmalot/2015/02/12/the-hepatitis-c-scorecard-gilead-is-trouncing-abbvie-but-at-a-price/>

⁴ IMS Health, "Comparison of Hepatitis C Treatment Costs," September 2016

https://www.irshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/fihi_Comparison_of_HepatitisC_Treatment_Costs.pdf

⁵ Kabiri M, Jazwinski AB, Roberts MS, Schaefer AJ, Chhatwal J. II1e Changing Burden of Hepatitis C Virus Infection in the United States: Model Based Predictions. *Annals of Internal Medicine*. 2014; 161 (3): 170



Studies have shown that the prevalence of Hepatitis C is much greater in the low-income population, a population especially susceptible to coverage "churn" such as transitions from Medicaid to no coverage or to corrections health care. Louisiana's laudable goal of eliminating Hepatitis C will rely on patients having access to continuous coverage for the duration of treatment.

Some options already exist to help the uninsured population, such as manufacturer-sponsored patient assistance programs that help uninsured and underinsured patients obtain medicines they need free or nearly free. While these programs provide medicine and peace of mind to millions of Americans seeking treatment, they cannot adequately address proper provider care management or provider continuity. Nor do they alleviate the stress patients may face when they lose healthcare coverage, experience temporary changes to income levels, or are placed in jail or prison.

In considering its options, Louisiana might ask which strategies would be the least disruptive to patients' course of treatment, as well as which would be most affordable and simple administratively for community providers. In addition, Louisiana might take into account which option would be most sustainable over time and incentivize providers to most properly and thoroughly treat to cure patients. In designing a program that would target the uninsured, we believe it would be important for the state to make sure it can appropriately identify the uninsured population - in order to provide such individuals with access to any state-negotiated benefits, and also in order to ensure that there are program integrity-related safeguards that ensure that persons who avail themselves of such a state-supported program are indeed uninsured.

PhRMA welcomes the opportunity to continue dialogue with you and other state administrators, and to assist in crafting solutions to make Hepatitis C treatments accessible for Louisianans.

Sincerely,

Kipp Snider

Vice President, State Policy